



Iowa Department of Human Services

Kim Reynolds
Governor

Adam Gregg
Lt. Governor

Jerry R. Foxhoven
Director

September 21, 2017

W. Charles Smithson
Secretary of the Senate
State Capitol Building
LOCAL

Carmine Boal
Chief Clerk of the House
State Capitol Building
LOCAL

Dear Mr. Smithson and Ms. Boal:

Enclosed please find copies of reports to the General Assembly relative to the Iowa Medicaid Fee-for-Service (FFS) Annual Drug Utilization Review (DUR) Report.

This report was prepared pursuant to the directive contained in Iowa Code 249A.24, subpart 3.

Pursuant to federal regulations the State agency administering Medicaid is mandated to perform a quality review. This review is the focus of the DUR program and the concentration is on evaluating and improving medication-use processes with the goal of optimal patient outcomes. With the focus on quality there are naturally some associated cost savings with the initiatives, as previously provided in the annual reports. As Medicaid preferred drug list (PDL) programs have matured and point of sale (POS) systems transmit advanced software edits, the ancillary cost savings attributed to patient and problem focused reviews by the DUR Commission have decreased. It is also difficult to attribute which pharmacy program changes resulted in the cost savings due to multiple concurrent initiatives that impact utilization and expenditures outside of the DUR.

Additionally in April 2016, the majority of Medicaid members began receiving their prescription drug benefits through the Managed Care Organizations (MCOs). Due to the temporary nature of the members in the FFS program, and the low number of members permanent to the FFS program, the number of initiatives performed in SFY17 and thus the associated cost savings, decreased. For SFY17, each MCO was required to conduct a DUR program within their member population. The outcomes of the MCO programs are not included in this report.

Activities of the DUR Commission were evaluated for SFY17 for interventions performed in the previous and the current fiscal year. The DUR Commission realized an overall direct cost savings of 29 cents for every dollar spent on the program administratively. State money for this program is matched by the federal government at a 1 to 1 ratio (federal to state), so savings can also be stated as 58 cents per state dollar spent. Total annualized cost savings estimates for SFY17 (\$77,776.09) were lower than SFY16 (\$7,111,493.58), a decrease of \$7,033,717.49. This decrease in cost savings is due largely to the MCO transition as previously noted, resulting in a decreased number of measurable interventions.

- Savings from patient-focused reviews for SFY17 (\$23,336.89) were lower than SFY16 (\$263,026.39), a decrease of \$239,689.50. This is the result of a decrease in the number of suggestions made and the number of suggestions accepted.
- Savings from problem-focused reviews for SFY17 (\$54,439.20) were lower than SFY16 (\$6,848,467.19), a decrease of \$6,308,275.51. This is the result of one problem-focused intervention being completed in the FFS program.

The Commission will continue their collaboration with the MCOs to determine the most efficient format to conduct DUR for the entire Iowa Medicaid population, while ensuring appropriate, cost-effective medication therapy.

Please feel free to contact me if you need additional information.

Sincerely,



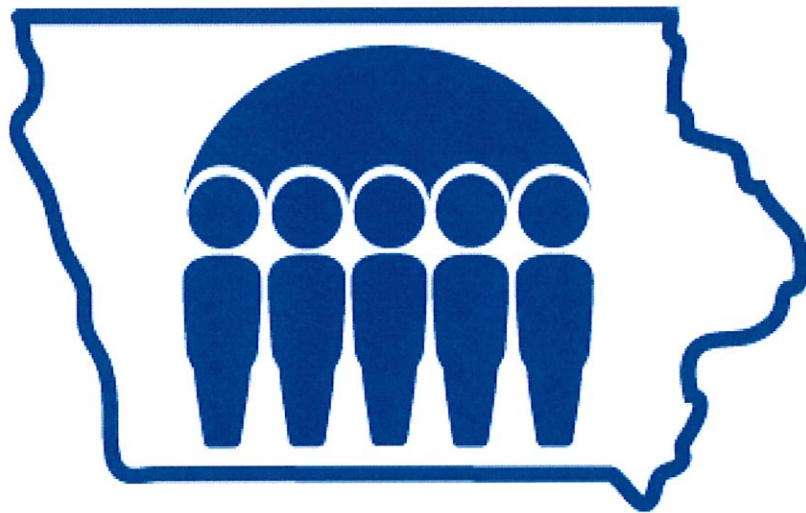
Merea Bentrott
Policy Advisor

MB:slp:ps

Enclosure

cc: Kim Reynolds, Governor
Senator Mark Costello
Senator Amanda Ragan
Representative David Heaton
Representative Lisa Heddens
Legislative Service Agency
Kris Bell, Senate Democrat Caucus
Josh Bronsink, Senate Republican Caucus
Carrie Malone, House Republican Caucus
Zeke Furlong, House Democrat Caucus

Iowa Department of Human Services



Iowa Medicaid Drug Utilization Review Commission Annual Report of Activities Fee-for-Service Program SFY17

September 30, 2017

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The Iowa Medicaid Drug Utilization Review Commission

Change Healthcare has developed the following report for the Iowa Department of Human Services. This report provides a summary description of the activities of the Iowa Medicaid Drug Utilization Review Commission, along with an evaluation of the Iowa Medicaid fee-for-service retrospective drug utilization review program. Information contained in this report covers projects completed and evaluated during the time period of July 2016 through June 2017. This report encompasses information pre- and post-managed care implementation.

Background Information

Established in 1984, the DUR Commission is charged with promoting the appropriate and cost-effective use of medications within the Iowa Medicaid member population. Acting as a professional advisory group, the Commission analyzes medication utilization by the members of Iowa Medicaid and performs educational initiatives to optimize member outcomes. The Commission performs retroDUR and educational outreach through patient-focused reviews and problem-focused reviews. The Commission supports the proDUR program through criteria review and acts as a resource to the DHS on other issues concerning appropriate medication use. On April 1, 2016, the Iowa Medicaid population transitioned to managed care. With this transition, roughly 90 percent of the population moved to managed care leaving 10 percent of the population in the fee-for-service (FFS) program. Due to the transition, the DUR Commission only has access to FFS claims, limiting the ability to perform patient-focused and problem-focused reviews at the same level prior to managed care. However, the Managed Care Organizations (MCOs) participate in the DUR Commission meetings, provide a bi-monthly prevalence report with information on prescribers, pharmacies and prescription claims information for the DUR Commission to review, and have the ability to provide input during the meetings. While the focus has shifted to the development of clinical prior authorization and ProDUR edits, collaboration with the MCOs continues to develop the most efficient way to perform retroDUR and educational outreach for the entire Iowa Medicaid population.

The MCOs are required to follow the FFS Preferred Drug List (PDL), prior authorization (PA) criteria and utilization edits. Additionally, each MCO was required to conduct a DUR program within their member population.

Patient-Focused Reviews

Prior to the managed care transition, patient-focused reviews were completed with the review of 300 member profiles at each meeting (six times annually). The DUR contractor generated these profiles through a complex screening process. The first step of the screening process subjects member profiles to a therapeutic criteria screen. If a profile is found to have failed one or more therapeutic criteria, the member profiles are then assigned a level of risk based on their medication history and potential for adverse events regarding medication. The profiles with the highest level of risk are then selected for the Commission to review. Six months of prescription claims data and medical claims data, if available, are assessed to determine this risk factor. Since the managed care transition, the remaining FFS population is run through the same complex screening process resulting in less than 300 member profiles meeting the criteria for review.

The member profiles selected from this process are manually reviewed by the Commission, if needed, or the DUR Coordinator to minimize false positives generated by the computer selection process. The Commission or DUR Coordinator identifies situations where educational intervention might be appropriate. Through these interventions, suggestions regarding medication therapy are communicated to the care providers. Templates are developed for suggestions that are frequently communicated to providers. The reviewer may also author an individualized suggestion if a template suggestion is not applicable.

Educational interventions are generally done by letters to prescribers and pharmacists, but may also be done by telephone or in person. The suggestions made by the Commission or DUR Coordinator are educational and informative in nature. Suggestions may be classified as either therapeutic or cost saving in nature. In addition, these suggestions are classified by problem identified for reporting purposes. The classifications are as follows:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration
- Unnecessary Drug Use
- Therapeutic Duplication
- High Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy
- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Suggestions are intended to promote appropriate and cost-effective use of medications. When suggestions result in cost savings, these savings are calculated based on decreased cost of medications. However, several of these classes of interventions are intended to increase the use of medications. Examples are member underuse and missing drug therapy. In these cases, the addition of medication therapy will increase medication expenditures, but will be beneficial to the member and should result in cost savings in medical services and/or improved quality of life. Cost savings in these situations cannot be calculated due to data limitations. Therefore, these suggestions are considered to have a positive impact on the program with no medication cost savings. Cost savings on medical services are assumed however not calculated.

Providers are invited to respond to the Commissions' suggestions and to request additional information. Responses are voluntary and response rates are calculated for prescribers and pharmacists.

Once a member's profile is reviewed, it is excluded from the selection process for nine months to eliminate repeat selections. After this waiting period, the current profile for each member is generated and reviewed to determine if the Commission's suggestion was implemented. If so, fiscal considerations resulting from that change are also calculated. The policy regarding these calculations is included in Appendix B.

Problem-Focused Reviews

Problem-focused reviews narrow the emphasis of review to a specific issue that has been determined to be an area where a targeted educational effort to providers may be valuable. Topics for review are selected from findings of patient-focused reviews or from reviews of medical literature. Criteria are developed to identify the members who may benefit from intervention and educational materials are disseminated to their providers. Providers are encouraged to voluntarily respond. The member profile is generated again in an appropriate amount of time (typically 6 to 9 months) to determine the impact rate of the intervention, along with any fiscal considerations. The policy regarding these calculations is also included in Appendix B.

Administrative Review

The Commission will review utilization data and medical literature to make recommendations to the Department of Human Services (DHS) regarding policy issues. These recommendations are made to promote the appropriate use of medications and positive member outcomes. Recommendations are made at the request of the DHS or at the Commission's discretion. All authority to accept or reject DUR Commission recommendations lies with the DHS. The Commission may make recommendations but does not make policy. Primary areas for recommendations include proDUR, drug prior authorization (PA), coverage of medications, and administrative and billing procedures. The prospective drug utilization review (proDUR) system is currently administered by Change Healthcare, and was implemented statewide in July 1997. The Commission reviews the criteria utilized by Change Healthcare and provides input regarding therapeutic validity. Special attention is given to eliminating false positive messaging.

The Commission recommends new or updated guidelines for use in the drug prior authorization program. This process is based on reviews of medical literature in addition to comparisons with other public and private sector programs. Input from providers outside the Commission, particularly specialists, is often sought when developing these guidelines. Once developed, the guidelines are sent to the medical and pharmacy associations in the state for comments. After considering these comments, a final recommendation is made to the Department. The Department may or may not accept the recommendation or may alter the recommendation.

The Commission also makes recommendations regarding coverage of medication or devices. As most coverage requirements are defined by OBRA '90, these recommendations generally encourage coverage of optional services. An example would be the coverage of select over-the-counter medications.

The Commission may review pharmacy claims with respect to administrative procedures. Situations where funding for medication can be obtained from other sources are relayed to the Department for their action. For instance, Medicare will pay for immunosuppressive medications for transplant patients and nebulizer solution for dual eligible patients. The Commission also identifies situations where the Department may recover funds from inappropriate billing.

Overall Results

Activities of the DUR Commission were evaluated for SFY17 for interventions performed in the previous or the current fiscal year. Due to the transition to managed care, savings to the state are significantly less than previous years. This is due to a period where prior to the transition, any review of pharmacy claims for the purpose of an educational intervention would result in members being lost at follow up due to the majority of the members being enrolled in a managed care organization (MCO). However, each MCO was required to conduct a DUR program within their member population. After the transition, the number of patient claim reviews decreased due to the shift of members to a MCO. The direct cost savings from all activities of the DUR Commission are calculated to be \$77,776.09* which equates to 29 cents* for every \$1.00 of combined federal and state dollars spent administratively. This calculation is based on estimates regarding two types of reviews: patient-focused reviews and problem-focused reviews. These results are also found in Appendix C.

Cost Savings Estimate	\$77,776.09*
Cost of the Program (state and federal dollars)	\$270,000.00
Net Cost Savings Estimate	(\$192,223.91)*
Savings per Total Dollar Spent (state and federal)	\$0.29*
Savings per State Dollar Spent	\$0.58*

Patient-focused reviews resulted in \$23,336.89* in direct cost savings, or \$97.64* per patient evaluated. This estimate is based on the 240 suggestions made by the DUR Commission identified from the review of the medication therapy of 239 patient profiles selected for intervention. Of these 240 suggestions, 24 suggestions were implemented by the providers, resulting in a 10 percent impact rate.

Patient-Focused Profile Review	
Suggestions Made	240
Therapy Changed	24
IMPACT RATE	10.0%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated	\$97.64*
Dollars Saved on Medication	\$23,336.89*

*Savings reported are pre-rebate, total dollars

Problem-focused reviews resulted in an estimated cost savings of \$54,439.20* or \$54,439.20 saved per patient evaluated. This estimate is based on the review of one patient profile with that patient selected for intervention. Therapy was changed for this one patient, resulting in an impact rate of 100 percent.

Problem-Focused Profile Review

Patients Evaluated	1
Therapy Changed	1
IMPACT RATE	100%

Cost Savings Estimates:

Dollars Saved per Patient Evaluated	\$54,439.20*
Dollars Saved on Medication	\$54,439.20*

Comparison to Previous SFY Report

Cost savings estimates for SFY17 (\$77,776.09*) are lower than last year. This decrease is due largely to the transition to managed care. With a fraction of members remaining in FFS, the number of interventions has significantly decreased limiting the ability to realize a substantial cost savings.

The savings from SFY17 patient-focused reviews (\$23,336.89*) were lower than SFY16 (\$263,026.39*), and the number of suggestions made (240) vs. (1,234) decreased as well as the number of suggestions that were accepted (24) vs. (61) from SFY16. Again, due to the transition to managed care, cost savings, the number of suggestions made and the number of suggestions accepted decreased. Historically there has been minimal impact from patient-focused reviews that is contributed to the maturation of the Preferred Drug List (PDL) program and Point of Sale (POS) edits that have been implemented over the years. It is difficult to determine the actual cause for the minimal number of suggestions accepted. One theory could be, due to the voluntary participation of the prescriber and lack of the ability to enforce the recommendations made by the DUR Commission, prescribers do not make the recommended change due to lack of time or they do not feel it is in the best interest of the patient.

The savings from problem-focused reviews for SFY17 (\$54,439.20*) were lower than SFY16 (\$6,848,467.19*). This again was due to the transition to managed care, with only one intervention being performed.

Results by Review Type

Patient-Focused Review

During this evaluation period, 586 educational intervention letters were mailed to prescribers and pharmacies regarding medication therapy. Of this total, 315 letters (53.75 percent) were mailed to prescribers, and 271 (46.25 percent) letters were mailed to pharmacies. Providers are invited to voluntarily respond to DUR Commission letters. Providers returned 306 responses to these letters, resulting in an overall response rate by the providers of 52.22 percent. Of this total, 186 (60.78 percent) responses were from prescribers and 120 (39.22 percent) were from pharmacies. The response rate differed between physicians and pharmacies; 59 percent for physicians and 44 percent for pharmacies.

In these 586 educational letters, the DUR Commission made 240 suggestions. Of these suggestions, 235 (97.92 percent) were therapeutic in nature while 5 (2.08 percent) were cost-saving in nature. The suggested change was implemented in 24 cases, resulting in an overall impact rate of 10 percent.

Of the 240 suggestions, four types of suggestions accounted for over 92 percent of the total. Those four suggestions were Patient Underuse (5.42 percent), Not Optimal Dose (2.5 percent), Therapeutic Duplication (73.33 percent), and Unnecessary Drug Therapy (11.25 percent). No other single category accounted for more than 3 percent of the total suggestions. Of the 24 changes, the most common reasons for the Commission's inquiry were Not Optimal Dose (4.17 percent), Therapeutic Duplication (83.33 percent), Unnecessary Drug Therapy (8.33 percent), and Not Optimal Duration (4.17 percent). No other single category accounted for any changes.

The suggestions that resulted in change the highest percentage of the time were Not Optimal Dose (16.67 percent), Therapeutic Duplication (11.36 percent), Unnecessary Drug Therapy (7.41 percent), and Not Optimal Duration (20 percent).

Implementation of therapeutic suggestions resulted in direct drug cost savings of \$23,336.89*. No cost-saving suggestions were suggested or implemented resulting in zero direct drug cost savings*. The total amount saved on medication utilization was calculated to be \$23,336.89* for the 240 patients evaluated, or \$97.64* per patient.

The complete details of the results of patient-focused studies reported bi-monthly are also outlined in Appendix D.

Problem-Focused Reviews

One problem-focused review was evaluated during SFY17. In conducting this study, one patient profile was reviewed and selected for intervention. This one case showed evidence of a positive outcome, resulting in an impact rate of 100 percent. This change in therapy resulted in annualized cost savings of \$54,439.20* or \$54,439.20* per patient evaluated.

*Savings reported are pre-rebate, total dollars

Results of this focus study are detailed in Appendix E. The purpose for the problem-focused review and a complete description of result is available in Appendix F.

Administrative Review

Prior Authorization

The DUR Commission annually reviews the prior authorization program for clinical appropriateness. Changes are recommended to the Department. During SFY17, the DUR Commission reviewed all therapeutic categories requiring prior authorization as well as therapeutic criteria to support operations of the Preferred Drug List. Recommendations for modifications to existing criteria and recommendations for new prior authorization criteria can be found in Appendix G as well as the Recommendation Letters.

Prospective Drug Review

The DUR Commission reviews and recommends prospective drug utilization review criteria to be used by the Department. Information regarding the DUR Commission recommendations for prospective DUR can be found in the DUR Recommendation Letters in Appendix G and the list of recommendations in Appendix H.

Other Activities

Three newsletters were written and posted to the website by the DUR Commission for the Medicaid provider community during this fiscal year.

The DUR Commission maintains a web site to improve communication with a variety of stakeholders. The web site is found at www.iadur.org. The site contains information regarding upcoming meeting dates, locations, agendas, minutes from the previous meeting, as well as past issues of the provider newsletter, the *DUR DIGEST*. In addition, the web site provides meeting agendas and minutes for the Drug Utilization Review Mental Health Advisory Group.

Brian Couse, M.D. completed his first term on the DUR in June 2017 and did not seek reappointment for a second term.

Larry Ambrosion, R.Ph. completed his second term on the DUR in June 2017 and did not seek reappointment for a third term.

Bimonthly prevalence reports were developed to allow the DUR Commission to analyze changes in medication use across the entire Medicaid patient population and can be viewed on the DUR Commission website as a part of the meeting materials.

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG) was established in SFY 2008. Descriptions of the program, as well as meeting minutes are found in Appendix J.

Periodically the DUR Commission will make recommendations to the Iowa Medicaid Pharmacy & Therapeutics Committee regarding the status of a medication on the Preferred Drug List (PDL). Recommendations can be found in Appendix K.

Links to useful items regarding the DUR Commission can be found in Appendix L, which include the DUR website, DUR newsletters, and Prevalence Reports.

Appendix A

Commission Members

**Iowa Medicaid Drug Utilization Review
Commission Members
2016-2017**

Larry Ambrosion, R.Ph.

Larry Ambrosion currently owns and operates The Medicine Shoppe Pharmacy in Newton, Iowa. Mr. Ambrosion graduated from the University of Iowa in 1992. He worked for Columbia Regional Hospital in Columbia, MO from 1992 to 1998. Mr. Ambrosion returned to Iowa in 1998 and opened The Medicine Shoppe. Mr. Ambrosion was reappointed for a second term in 2013 which expired in June 2017. Mr. Ambrosion did not seek a third term.

Laurie Anderson, Pharm.D

Dr. Anderson is the pharmacy manager at Hy-Vee in Red Oak, Iowa. She graduated with her Doctor of Pharmacy degree from Creighton University in 2000. She served on the Board of Professional Affairs as a member of the Iowa Pharmacy Association in 2006. Dr. Anderson has experience with both long-term care and retail pharmacy. Dr. Anderson was reappointed for a third term in 2015 which will expire in June 2019.

Brian Couse, M.D.

Dr. Couse graduated from the University of Nebraska College of Medicine in 1998. He then completed his Primary Care Rural Training Residency Program in 2001 and is board certified in Family Medicine. Dr. Couse currently sees patients at the Methodist Physicians Clinic in Red Oak, Iowa. He treats patients of all ages and has clinical areas of interest in obstetric care including deliveries and C-sections and upper and lower gastrointestinal endoscopy. Dr. Couse was appointed to the DUR Commission in 2013; His first term expired in June 2017. Dr. Couse did not seek a second term.

Brett Faine, Pharm.D.

Dr. Faine is a Clinical Pharmacy Specialist in Emergency Medicine at the University of Iowa Hospital. He serves as a preceptor to residents and Pharm.D. students in the Emergency Treatment Center. Dr. Faine received his Pharm.D. degree from University of Iowa and completed an ASHP-accredited PGY1 Pharmacy Residency at the University of Iowa Hospitals and Clinics. Dr. Faine was reappointed for a second term in 2014 which will expire in June 2018.

Daniel Gillette, M.D.

Dr. Gillette completed his undergraduate work at Yankton College, where he graduated Magna Cum Laude as valedictorian in 1985. He then attended medical school at the University of Nebraska, followed by a residency at the University of Kansas, and a fellowship at the University of New Mexico. He is board certified in General Psychiatry, as well as Child and Adolescent Psychiatry, and also has a Master's degree in Health Care Management from the Harvard School of Public Health. During his 10 years at the Cherokee Mental Health

Institute he served in several roles, including Clinical Director and Superintendent. Currently, in addition to offering direct clinical psychiatric care at Dean and Associates and Opportunities Unlimited, he is Senior Physician Leader of Behavioral Health for UnityPoint Health - St. Luke's in Sioux City, past president of the Iowa Psychiatric Society, and provides clinical consultation for Wellmark Blue Cross Blue Shield of Iowa and South Dakota. Dr. Gillette was appointed to the DUR Commission in 2015; his first term will expire in June 2019.

Mark Graber, M.D., FACEP, MSHCE

Dr. Graber is a Professor of Emergency Medicine and Family Medicine at the University of Iowa Carver College of Medicine. Dr. Graber graduated from Eastern Virginia Medical School and completed his Family Practice Residency at the University of Iowa. In addition to his clinical duties, Dr. Graber serves as an advisor to medical students and residents, and has published numerous text books, reviews, and papers in publications such as *The Annals of Pharmacotherapy*, *Emergency Medicine*, and *American Family Physician*. Dr. Graber also serves as an associate Clinical Editor of the Prescribers Letter. Through his travels, Dr. Graber has presented throughout the United States as well as Ukraine, Russia, and China. In 2007, Dr. Graber was honored by appearing on the "Best Doctors in America" list. Dr. Graber was reappointed for a third term in 2016 which will expire in June 2020.

Kellen Ludvigson, Pharm.D.

Dr. Ludvigson graduated with distinction from the University of Iowa College of Pharmacy in 2007, and he is kept busy working full-time at three different independent pharmacies: both the Holstein and Cherokee branches of Main Street Pharmacy, and also the Cherokee Mental Health Institute in Cherokee. Additionally, he is employed as a relief pharmacist at the Sioux City Target. This diversity in employment allows him to encounter a variety of prescribers and patients in the Medicaid program, and has resulted in a great deal of experience with the Iowa Medicaid PDL. Dr. Ludvigson was reappointed for a second term in 2016 which will expire in June 2020.

Susan Parker, Pharm.D.

Dr. Parker is the Pharmacy Director for the Department of Human Services at the Iowa Medicaid Enterprise and serves as liaison to the Commission. She graduated with a Doctor of Pharmacy degree from Mercer Southern School of Pharmacy in Atlanta, Georgia. She is also a graduate of Gannon University in Erie, Pennsylvania with a Bachelor of Science Degree Physician Assistant. Dr. Parker brings to the Commission a variety of experience in health care as an Iowa Medicaid drug prior authorization pharmacist, community pharmacist, and physician assistant. She is a member of the American Medicaid Pharmacy Administrators Association and the Western Medicaid Pharmacy Administrators Association.

Jason Wilbur, M.D.

Dr. Wilbur graduated from the Saint Louis University School of Medicine in 1999. He then completed his Family Medicine Residency at the University of Iowa, where he was Chief Resident 2001-2002, followed by a Geriatric Medicine Fellowship 2002-2003. He is currently Associate Professor of Clinical Family Medicine for the Roy J. & Lucille A. Carver College of Medicine at the University of Iowa. Prior to that, he was Medical Director of the Family Medicine Clinic in Iowa City from 2006 to 2011. The University of Iowa Hospitals and Clinics awarded him the Above and Beyond Reward in 2006 and again in 2007, along with the Teacher of the Year Award, presented by the University of Iowa Family Medicine residents, in 2008. Dr. Wilbur was reappointed for a second term in 2016 which will expire in June 2020.

Appendix B

Evaluation Procedure

EVALUATION OF THE IMPACT OF PROSPECTIVE AND RETROSPECTIVE DRUG UTILIZATION REVIEW INTERVENTIONS

The goal of Drug Utilization Review (DUR) is to evaluate cost savings and provide quality assurance of medication use. The DUR Commission works in conjunction with the pharmacy medical program at the Iowa Medicaid Enterprise to contribute to the overall success of the program. The Drug Utilization program:

- Evaluates three areas of activity including Patient-focused Drug Utilization Reviews, Problem-focused Drug Utilization Reviews, and Administrative Activities.
- Examines only direct drug costs. DUR evaluation does not have the ability to quantify its impact on other health services such as hospitalizations, ER visits, and physician visits.
- Reports pre-rebate savings since access to supplemental rebates is not within the scope of the DUR program.
- Often provides recommendations that are qualitative, such as improved health outcomes, rather than quantitative in nature.

As a general principle, evaluations are based upon an observed change in the targeted prescribing or dispensing pattern, as well as changes seen in therapy of the individual patients. One evaluation approach is to observe and quantify changes in prescribing due to a given intervention compared to a control group of providers who do not receive the intervention. The intervention's impact on prescribing may be more readily detectable by this method and could be measured by comparing the two groups of patients or prescribers. However, it is very difficult to design a scientifically sound control group given the many variables surrounding patient care. Therefore, in most instances the DUR Commission has chosen to forego use of a control group to achieve the greatest impact. Although the evaluation of the intervention may be less scientific, intervention on behalf of all the patients is more desirable. In this instance, prescribing trends may not be available for comparison, but savings and benefit can still be quantified at the individual patient level.

Patient-focused DUR

Patient-focused DUR concentrates efforts on specific suggestions made about an individual patient. Each suggestion, or template, attempts to make a change in therapy. These changes are either therapeutic or cost-saving in nature; however, these situations are not necessarily mutually exclusive. A therapeutic change -- one that improves the patient's therapy in some way -- may also produce cost savings. Cost-saving changes are attempted when a patient is not receiving a medication in the most economical form. The intervention does not change the medication but points out that the same medication could be given in a more cost-effective manner. Each template and intervention is evaluated to determine if the proposed change was implemented and, if so, what economic implications can be calculated.

The calculation relating to therapeutic and cost saving interventions is tabulated by comparing a member's initial profile with the member's re-review profile. Each member profile is a six-month snapshot of medications covered by the Medicaid program. Pertinent information such as patient name and ID, date of service, drug name, strength, and quantity, RX number, day supply, prescriber and pharmacy ID, total price submitted, and amount paid appear on each profile. There are nine months in between the initial and re-review profiles to accommodate for provider review, response, and implementation for therapeutic and or cost changes. For each intervention, the total amount paid on the initial profile for any one intervention is noted. According to the intervention at hand, the re-review profile is evaluated for change. The amount paid on the re-review profile for the same intervention is also noted. A comparison between the profiles is calculated by subtracting the total amount paid from the initial profile with the total amount paid from the re-review profile. This calculation is then annualized multiplying the number by 2 to get the pre-rebate annualized savings. Consider this *cost saving* example:

Template sent to the provider:

According to the profile, this patient is receiving Lexapro 10mg tablets. Substantial cost savings can be realized by using one-half of a Lexapro 20mg tablet which is scored and easily broken. Would this patient be a good candidate for this cost-saving measure?

Information on initial profile sent to provider:

Lexapro 10 mg #30= \$83.04
Lexapro 10 mg #30= \$83.04
Lexapro 10 mg #30= \$83.04
Lexapro 10 mg #30= \$83.04
Lexapro 10 mg #30= \$83.04
Lexapro 10 mg #30= \$83.04

Total Amount Paid \$498.24

Information on re-review profile used internally for evaluation:

Lexapro 20 mg #15 = \$45.92
Lexapro 20 mg #15 = \$45.92
Lexapro 20 mg #15 = \$45.92
Lexapro 20 mg #15 = \$45.92
Lexapro 20 mg #15 = \$45.92
Lexapro 20 mg #15 = \$45.92

Total Amount Paid \$275.52

Calculation of annualized savings

\$498.24 - \$275.52 = \$222.72 (savings for 6 months)

\$222.72 x 2 = \$445.44 (savings for 12 months)

Reported total pre-rebate annualized savings is \$445.44

All savings for patient-focused review are based on annualized savings for one year only. Reporting on patient-focused interventions will provide the following information:

- Total number of templates mentioned
- Number of templates that were therapeutic in nature
- Number of templates that were cost-saving in nature
- Total number of changes implemented
- Number of changes that were therapeutic in nature
- Number of changes with positive impact without savings
- Number of changes that were cost-saving in nature
- Total dollars saved from therapeutic changes
- Total dollars saved from cost-saving changes
- Total dollars saved
- Impact of interventions expressed as a percentage

All templates are described by one of sixteen classifications. These classifications indicate the general type of intervention addressed by the template. Reports will also include a breakdown by classification (therapeutic or cost-saving) of the templates used in the patient-focused letters. This data will show which templates are cited most often, result in change most often, and result in higher cost savings.

Templates that are therapeutic in nature include:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration of Use
- Unnecessary Drug Use
- Therapeutic Duplication
- High Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy

Templates that are cost saving in nature include:

- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Problem-focused DUR

Problem-focused DUR concentrates efforts on a specific problem or trend in prescribing. While patient-focused reviews may address a multitude of situations, a problem-focused review addresses only one concern. The DUR Commission uses guidelines, literature and peer-group prescribing to identify particular clinical situations that need addressed. This process ensures that each intervention is unique due to the subject matter and may differ in steps of evaluation.

Reporting for problem-focused interventions will include the types of intervention done and the resulting savings. Savings are always calculated based on one year of therapy only and are calculated in the same manner as explained in the patient-focused DUR section.

Administrative Review

The Drug Utilization Review (DUR) program is a component of the Pharmacy Medical Division of the Iowa Medicaid Enterprise (IME). DUR contributes expertise and information that leads to implementation in other programmatic areas including, but not limited to: Prospective Drug Utilization Review, Prior Authorization, Preferred Drug List, Disease Management, and Supplemental Rebates. Although the DUR program impacts all of the different pharmacy programs it is difficult to determine where its impact begins and ends. Therefore, the savings associated with DUR contribution in other pharmacy areas cannot be determined. IME pharmacy programs are listed below along with a DUR impact statement and example:

- Prospective DUR

Definition: A process in which a request for a drug product for a particular patient is screened for potential drug therapy problems before the product is dispensed.

Impact: The DUR Commission reviews scientific literature regarding specific medications and makes recommendations to DHS on appropriate utilization guidelines or parameters.

Example: The DUR Commission recommended that an age edit be placed on Provigil®, restricting its use in patients to those 16 years of age and older.

- Prior Authorization

Definition: A process for obtaining approval for a drug before the drug is provided to a member, as a precondition for provider reimbursement. Prior authorization is requested at the prescriber level and is a prescriber fax-only system using the forms provided by the Iowa Medicaid Enterprise.

Impact: The DUR Commission develops sound, cost-effective medication use guidelines by reviewing peer reviewed medical information from various sources. The Commission seeks outside expertise when necessary and considers public comments prior to

recommending step therapy for appropriate drug use.

Example: The DUR Commission developed the criteria for the Nicotine Replacement Therapy prior authorization.

Prior Authorization is required for over-the-counter nicotine replacement patches and nicotine gum. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment in the Quitline Iowa counseling program is required for approval.
- 3) Approvals will only be granted for patients eighteen years of age and older.
- 4) The maximum allowed duration of therapy is twelve weeks within a twelve-month period.
- 5) A maximum quantity of 14 nicotine replacement patches and/or 110 pieces of nicotine gum may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4 week supply at one unit per day of nicotine replacement patches and/or 330 pieces of nicotine gum. Following the first 28 days of therapy, continuation is available only with documentation of ongoing participation in the Quitline Iowa program.

- Preferred Drug List (PDL)

Definition: A list comprised of drugs recommended to the Iowa Department of Human Services by the Iowa Medicaid Pharmaceutical and Therapeutics Committee that have been identified as being therapeutically equivalent within a drug class and that provide cost benefit to the Medicaid program.

Impact: The DUR Commission makes referrals to and considers requests from the Pharmacy and Therapeutics (P&T) Committee to improve drug therapy.

Example: The DUR Commission recommended that the Iowa Medicaid Pharmacy and Therapeutics Committee change the status of products containing carisoprodol on the PDL from preferred to nonpreferred.

- Disease management

Definition: A coordinated process by which Iowa Medicaid identifies and treats diseases within defined patient populations. This goal is achieved by identifying and delivering the most effective and efficient combination of available resources.

Impact: The Commission reviews disease state guidelines to determine appropriate drug use, shares drug utilization information, and makes recommendations to improve therapeutic outcomes.

Example: DUR exchanged patient specific information with case management regarding utilization patterns of Advair®.

- Supplemental rebates

Definition: A rebate given in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).

Impact: The existence of a supplemental rebate and how it may impact the price of a medication is taken into consideration when the DUR Commission makes recommendations.

Example: The DUR Commission requested that the Iowa Medicaid P&T Committee review the different dosage forms of nicotine replacement therapy and share information as to which products were the most cost effective.

Appendix C

Overall Programs Results

**Program Evaluation/Cost Savings Estimates
Iowa Medicaid Retrospective Drug Utilization Review
Annual Report
SFY17**

Patient Focused Profile Review

Suggestions Made	240
Therapy Changed	24
Impact Rate	10.00%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	\$97.64
Dollars Saved on Medication*	\$23,336.89

Problem-Focused Profile Review

Suggestions Made	1
Therapy Changed	1
Impact Rate	100.00%
Cost Savings Estimates:	
Dollars Saved per Patient Evaluated*	\$54,439.20
Dollars Saved on Medication*	\$54,439.20

Cost Savings Estimate*	\$77,776.09
Cost of the Program (State & Federal)	\$270,000.00
Net Cost Savings Estimate	(\$192,223.91)

Savings Per Dollar Spent (State and Federal)* **\$0.29**

Savings Per State Dollar Spent* **\$0.58**

*Savings reported are pre-rebate, total dollars

Appendix D Results Patient-Focused

Patient - Focused Reviews

SFY17

Initial Review Date

October 2015 - September 2016

Re-review Date

July 2016 - June 2017

Patient Profiles Reviewed	549
Profiles Selected for Intervention	239

Intervention Letters Sent

Prescribers	315	53.75%
Pharmacists	271	46.25%
Total	586	100%

Responses Received

Prescribers	186	60.78%	Overall Response Rate	52.22%
Pharmacists	120	39.22%	Prescriber Response Rate	59.05%
Total	306	100.00%	Pharmacy Response Rate	44.28%

Total Number of Suggestions

Therapeutic	235	97.92%
Cost-Saving	5	2.08%
Total	240	100%

Total Number of Changes

Therapeutic	24	100.00%	Impact Rate	10.00%
Cost-Saving	0	0.00%		
Positive Impact Only	0	0.00%		
Total	24	100%		

Patient - Focused Review
Month by Month Breakdown
SFY17

Initial Review Date Evaluation Date	Oct-15 Jul-16	Dec-15 Sep-16	Feb-16 Nov-16	Apr-16 Jan-17	Jun-16 Mar-17	Aug-16 May-17	Total
Profiles Reviewed	300	0#	0#	0#	235	14	549
Profiles Available for Evaluation	195	0	0	0	42	2	239
Total Number of Suggstions Made	195	0	0	0	42	3	240
Therapeutic	191	0	0	0	41	3	235
Cost Saving	4	0	0	0	1	0	5
Total Number of Changes Made	7	0	0	0	16	1	24
Therapeutic	7	0	0	0	16	1	24
Cost Saving	0	0	0	0	0	0	0
Positive Impact Only	0	0	0	0	0	0	0
Total Dollars Saved - Therapeutic	\$12,199.93	\$0.00	\$0.00	\$0.00	\$10,893.73	\$243.23	\$23,336.89
Total Dollars Saved - Cost Saving	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Total Dollars Saved on Medication*	\$12,199.93	\$0.00	\$0.00	\$0.00	\$10,893.73	\$243.23	\$23,336.89
Total Dollars Saved per Profile	\$62.56	#DIV/0!	#DIV/0!	#DIV/0!	\$259.37	\$121.62	\$97.64

*Savings reported are pre-rebate total dollars.

**Medicaid DUR Impact Assessment
ReportPatient-Focused Reviews SFY17**

Initial Review Date Evaluation Date	Oct-15 Jul-16	Dec-15 Sep-16	Feb-16 Nov-16	Apr-16 Jan-17	Jun-16 Mar-17	Aug-16 May-17	Total	
Profiles Reviewed	300	0	0	0	235	14	549	
Profiles Evaluated	195	0	0	0	42	2	239	
<u>Letters Sent</u>	485	0	0	0	93	8	586	100.00%
Prescribers	280	0	0	0	50	5	315	53.75%
Pharmacy	225	0	0	0	43	3	271	46.25%
<u>Responses Received</u>	151	0	0	0	153	2	306	100.00%
Prescribers	92	0	0	0	93	1	186	60.78%
Pharmacy	59	0	0	0	60	1	120	39.22%
Total Number of Templates Mentioned	195	0	0	0	42	3	240	100.00%
Therapeutic	191	0	0	0	41	3	235	97.92%
Cost-Saving	4	0	0	0	1	0	5	2.08%
Total Number of Changes Made	7	0	0	0	16	1	24	100.00%
Therapeutic	7	0	0	0	16	1	24	100.00%
Cost-Saving	0	0	0	0	0	0	0	0.00%
Positive Impact Only	0	0	0	0	0	0	0	0.00%
Total Dollars Saved - Therapeutic Changes	\$12,199.93	\$0.00	\$0.00	\$0.00	\$10,893.73	\$243.23	\$23,336.89	100.00%
Total Dollars Saved - Cost Saving Changes	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	0.00%
Total Dollars Saved on Medication*	\$12,199.93	\$0.00	\$0.00	\$0.00	\$10,893.73	\$243.23	\$23,336.89	100.00%
Total Dollars Saved Per Profile Evaluated	\$62.56	#DIV/0!	#DIV/0!	#DIV/0!	\$259.37	\$121.62	\$97.64	

*Savings reported are pre-rebate, total dollars

Comment Type
Patient Focused Reviews
SFY17

Initial Review Date	Oct-15	Dec-15	Feb-16	Apr-16	Jun-16	Aug-16	Total	
Evaluation Date	Jul-16	Sep-16	Nov-16	Jan-17	Mar-17	May-17		
Template Classification	Suggestions	Changes	Suggestions	Changes	Suggestions	Changes	Suggestions	Changes
Adverse Drug Reaction	0	0	0	0	0	0	0	0
Drug-Disease Interaction	0	0	0	0	0	0	0	0
Drug-Drug Interaction	3	0	0	0	0	0	3	0
High Cost Drug	0	0	0	0	0	0	0	0
Inappropriate Billing	1	0	0	0	0	0	1	0
Missing Drug Therapy	0	0	0	0	0	0	0	0
Not Optimal Dosage Form	2	0	0	0	1	0	3	0
Not Optimal Dose	5	0	0	0	1	1	6	1
Not Optimal Drug	2	0	0	0	2	0	4	0
Not Optimal Duration	4	0	0	0	1	1	5	1
Patient Overuse	1	0	0	0	0	0	1	0
Patient Underuse	9	0	0	0	4	0	13	0
Potential Generic Use	1	0	0	0	0	0	1	0
Therapeutic Alternative	0	0	0	0	0	0	0	0
Therapeutic Duplication	143	5	0	0	30	14	176	20
Unnecessary Drug Therapy	24	2	0	0	3	0	27	2
Total	195	7	0	0	42	16	240	24

**Patient Focused Reviews
SFY17**

Template Classification	Total Suggestions	Total Changes	% of Total Suggestions	% of Total Changes	% of Suggestions Changed	% Dollars Saved
Adverse Drug Reaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Disease Interaction	0	0	0.00%	0.00%	0.00%	0.00%
Drug-Drug Interaction	3	0	1.25%	0.00%	0.00%	0.00%
High Cost Drug	0	0	0.00%	0.00%	0.00%	0.00%
Inappropriate Billing	1	0	0.42%	0.00%	0.00%	0.00%
Missing Drug Therapy	0	0	0.00%	0.00%	0.00%	0.00%
Not Optimal Dosage Form	3	0	1.25%	0.00%	0.00%	0.00%
Not Optimal Dose	6	1	2.50%	4.17%	16.67%	0.45%
Not Optimal Drug	4	0	1.67%	0.00%	0.00%	0.00%
Not Optimal Duration	5	1	2.08%	4.17%	20.00%	11.67%
Patient Overuse	1	0	0.42%	0.00%	0.00%	0.00%
Patient Underuse	13	0	5.42%	0.00%	0.00%	0.00%
Potential Generic Use	1	0	0.42%	0.00%	0.00%	0.00%
Therapeutic Alternative	0	0	0.00%	0.00%	0.00%	0.00%
Therapeutic Duplication	176	20	73.33%	83.33%	11.36%	76.10%
Unnecessary Drug Therapy	27	2	11.25%	8.33%	7.41%	11.78%
Total	240	24	100.00%	100.00%	10.00%	100.00%

Prepared by the Iowa Medicaid Drug Utilization Review Commission

Savings By Template Class
SFY17

Initial Review Date Evaluation Dte	Oct-15 Jul-16	Dec-15 Sep-16	Feb-16 Nov-16	Apr-16 Jan-17	Jun-16 Mar-17	Aug-16 May-17	Total
<u>Template Classification</u>							
Adverse Drug Reaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Drug-Disease Interaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Drug-Drug Interaction	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
High Cost Drug	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Inappropriate Billing	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Missing Drug Therapy	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Dosage Form	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Dose	\$0.00	\$0.00	\$0.00	\$0.00	\$105.70	\$0.00	\$105.70
Not Optimal Drug	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Not Optimal Duration	\$0.00	\$0.00	\$0.00	\$0.00	\$2,723.85	\$0.00	\$2,723.85
Patient Overuse	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Patient Underuse*	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Potential Generic Use	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Therapeutic Alternative	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Therapeutic Duplication	\$9,451.67	\$0.00	\$0.00	\$0.00	\$8,064.18	\$243.23	\$17,759.08
Unnecessary Drug Therapy	\$2,748.26	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$2,748.26
Total	\$12,199.93	\$0.00	\$0.00	\$0.00	\$10,893.73	\$243.23	\$23,336.89

*additional cost but positive impact assumed

Appendix E

Results Problem-Focused

Problem-Focused Studies
Impact Rate
SFY 2017

Focus	Review Period	Evaluation Period	Patients Evaluated	Positive Impact	Impact Rate
Lamictal Dose Consolidation	1/17/2017	5/17/2017	1	1	100.00%
TOTAL			1	1	100.00%

Problem-Focused Studies
SFY 2017

Focus	Review Period	Evaluation Period	Patients Reviewed	Patients Selected	Cost Savings Calculated
Lamictal Dose Consolidation	42752	42872	1	1	\$54,439.20

TOTAL			1	1	\$54,439.20 *
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* Savings reported are pre-rebate, total dollars.

Prepared by the Iowa Medicaid Drug Utilization Review Commission

Appendix F

Descriptions Problem-Focused

Description of Problem Focused Studies SFY17

Due to the transition to Managed Care on April 1, 2016, there was only one problem focus study conducted during SFY17.

This initiative was identified through the review of monthly paid claims where it was noticed a large cost and quantity dispensed for Lamictal 25mg tablets. Upon review, one member was identified as receiving this medication. The prescriber's office was contacted to gather additional information. A letter was sent to the prescriber asking if the patients dose could be consolidated to using a combination of Lamictal 200mg tablets and Lamictal 25mg tablets to obtain the prescribed daily dose. Upon re-review, the medication was changed to the recommended dose consolidation with an annualized savings of \$54,439.20.

Appendix G

Prior Auth Recommendations

Prior Authorization Criteria Review SFY17

During the fiscal year ending 2017, the Commission reviewed the following categories of medications covered under the prior authorization program. Criteria can be reviewed in the following recommendation letters.

DUR Meeting	New PA Criteria	Updated PA Criteria
08/03/2016	<ul style="list-style-type: none"> • Topical Acne & Rosacea Products (replaced Anti-Acne Topical Products and Topical Retinoids for Acne) • Novel Oral Anticoagulants • Potassium Binders • Meprpolizumab (Nucala) 	
10/05/2016	<ul style="list-style-type: none"> • Lupron Depot – Pediatric • Lupron Depot - Adult 	<ul style="list-style-type: none"> • Short-Acting Opioids • Buprenorphine/Naloxone
12/07/2016		<ul style="list-style-type: none"> • Omalizumab (Xolair) • Oral Constipation Agents • Multiple Sclerosis Agents - Oral
02/01/2017	<ul style="list-style-type: none"> • Daclizumab (Zinbryta) • Narcan (Naloxone) Nasal Spray 	<ul style="list-style-type: none"> • Alpha₂ Agonists, Extended Release
04/05/2017	<ul style="list-style-type: none"> • Eteplirsen (Exondys 51) 	<ul style="list-style-type: none"> • Insulin, Pre-Filled Pens • Hepatitis C Treatments • Lumacaftor/Ivacaftor (Orkambi)
06/07/2017	<ul style="list-style-type: none"> • GLP-1 Agonist/Basal Insulin Combinations • Calcifediol (Rayalde) • Lesinurad (Zurampic) • Sapropterin (Kuvan) 	



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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DUR Project Coordinator

August 4, 2016

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 3, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Topical Acne and Rosacea Products; Novel Oral Anticoagulants (NOACs); Patiromer (Veltassa); and Mepolizumab (Nucala). The DUR Commission members also made a recommendation to implement a ProDUR quantity limit on all strengths of rivaroxaban (Xarelto). The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a June 6, 2016 letter that was sent to them detailing the proposed criteria for Topical Acne and Rosacea Products; NOACs; Patiromer (Veltassa); and Mepolizumab (Nucala) as well as the proposed quantity limits for rivaroxaban (Xarelto).

Topical Acne and Rosacea Products (replaces Anti-Acne Topical Products and Topical Retinoids for Acne prior authorizations)

Newly Proposed Prior Authorization Criteria (combined for topical antibiotics and topical retinoids)

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. Documentation of diagnosis.
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid for moderate to severe acne.
3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).

4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.
7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.
8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Novel Oral Anticoagulants (removal of PA criteria for Pradaxa and Xarelto and combination of existing criteria for remaining non-preferred agents)

Newly Proposed Prior Authorization Criteria for Non-Preferred NOACs

Prior authorization is not required for preferred novel oral anticoagulants (NOACs). Prior authorization is required for non-preferred NOACs. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications under the following conditions:

1. Patient does not have a mechanical heart valve; and
2. Patient does not have active bleeding; and
3. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA₂DS₂-VASc score ≥ 1 ; and
4. A recent creatinine clearance (CrCl) is provided; and
5. A recent Child-Pugh score is provided; and
6. Patient's current body weight is provided; and
7. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs.
8. For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

In addition to the above PA criteria the DUR Commission made the recommendation to implement the following ProDUR quantity limits on rivaroxaban (Xarelto):

- 10mg tablet – 30 tablets per 30 days
- 15mg tablets – allow twice daily dosing for 21 days followed by once daily dosing
- 20mg tablets – 30 tablets per 30 days

Potassium Binders

Newly Proposed Prior Authorization Criteria

Prior authorization (PA) is required for non-preferred potassium binders. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of chronic hyperkalemia; and
3. Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Mepolizumab (Nucala)

Newly Proposed Prior Authorization Criteria

Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions:

1. Patient is 12 years of age or older; and
2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and
3. Patient has a pretreatment blood eosinophil count of ≥ 150 cells per μL within the previous 6 weeks or blood eosinophils of ≥ 300 cells per μL within 12 months prior to initiation of therapy; and
4. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta₂-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and
5. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an LABA and LTRA; and
6. A pretreatment forced expiratory volume in 1 second (FEV_1) $< 80\%$ predicted; and
7. Prescriber is an allergist, immunologist, or pulmonologist; and
8. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

1. Patient continues to receive therapy with an ICS, LABA and LTRA; and
2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or
3. Patient has experienced a decrease in administration of rescue medication (albuterol); or
4. Patient has experienced a decrease in exacerbation frequency; or
5. Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

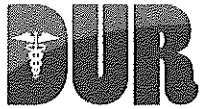
Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Acne and Rosacea Products; NOACs; Patisomer (Veltassa); Mepolizumab (Nucala) as well as the recommended quantity limits for rivaroxaban (Xarelto).

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." in a cursive script.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME



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October 6, 2016

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, October 5, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Lupron Depot Pediatric; Lupon Depot Adult; Short-Acting Opioids; and Buprenorphine/Naloxone. The DUR Commission members also made a recommendation to implement a ProDUR quantity limit on the following agents: loperamide 2mg tablet/capsule and loperamide 1mg/5ml. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an August 8, 2016 letter that was sent to them detailing the proposed criteria for Lupron Depot Pediatric; Lupron Depot Adult; Short-Acting Opioids; and Buprenorphine/Naloxone as well as the proposed quantity limits for: loperamide 2mg tablet/capsule, loperamide 1mg/5ml.

Lupron Depot - Pediatric

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of central precocious puberty (CPP); and
2. Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and
3. Patient is currently < 11 years of age for females or < 12 years of age for males; and
4. Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and
5. Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and

6. Baseline evaluations including the following have been conducted and/or evaluated:
 - a. Height and weight measurements; and
 - b. Sex steroid (testosterone or estradiol) levels have been obtained; and
 - c. Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and
 - d. Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and
 - e. Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and
 - f. Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and
7. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

When criteria for coverage are met, an initial authorization will be given for 6 months.

Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.

Lupron Depot - Adult

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. Patient is 18 years of age or older; and
2. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
3. Patient has a diagnosis of endometriosis for whom therapy with NSAIDs and at least one preferred 3 month course of a continuous hormonal contraceptive has failed; or
4. Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or
5. Patient has a diagnosis of advanced prostate cancer.

Therapy will be limited as follows:

- Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.
- Uterine leiomyomata – 3 month approval.
- Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).

Short- Acting Opioids

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for all non-preferred short acting *opioids*. Payment will be considered *under the following conditions*:

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two non-opioid pharmacologic therapies (acetaminophen or NSAIDs); and*
4. *Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring program website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a short-acting opioid is appropriate for this member.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

Buprenorphine/Naloxone

Newly Proposed Clinical Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for *oral* buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. *Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's*

medical benefit. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of opioid dependence and is 16 years of age or older; AND
2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND
3. Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy; AND
4. A projected treatment plan is provided, including:
 - Anticipated induction/stabilization dose,
 - Anticipated maintenance dose,
 - Expected frequency of office visits, and
 - Expected frequency of counseling/psychosocial therapy visits; AND
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. Requests for buprenorphine will only be considered for pregnant patients.

Requests for renewal must include:

- An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,
- Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,
- Documentation of a current, negative drug screen,
- Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.
- *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

Additionally, the DUR Commission recommends ProDUR quantity limits on the following agents:

- loperamide 2mg tablet/capsule – 4 tablets/capsules per day (120 units/30days)
- loperamide 1mg/5ml – 40 ml per day (1200ml/30 days)

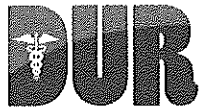
Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Lupron Depot Pediatric; Lupon Depot Adult; Short-Acting Opioids; and Buprenorphine/Naloxone as well as the recommended quantity limits for loperamide.

Sincerely,



Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME



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December 8, 2016

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, December 7, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Omalizumab (Xolair); Oral Constipation Agents; and Multiple Sclerosis Agents, Oral. Additionally, the DUR Commission members also made a recommendation to implement the following ProDUR edits: a morphine milligram equivalent (MME) per day limit across the opioid drug class and a quantity limit on Narcan Nasal Spray. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an October 7, 2016 letter that was sent to them detailing the proposed criteria for Omalizumab (Xolair); Oral Constipation Agents; and Multiple Sclerosis Agents, Oral as well as the proposed morphine milligram equivalent (MME) per day limit across the opioid drug class and the quantity limit on Narcan Nasal Spray.

Omalizumab (Xolair)

Proposed Clinical Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and
2. Patient is 6 years of age or older; and
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. Pretreatment IgE level is *within the following range:*

- a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
- b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
5. Patient's weight is within the following range:
 - a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
 - b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and*
6. History of positive skin or RAST test to a perennial aeroallergen; and
7. Prescriber is an allergist, immunologist, or pulmonologist; and
8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, *AND a leukotriene receptor antagonist*, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and
9. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.*
10. Patient has access to an *epinephrine injection* to treat allergic reactions that may occur after administration of Xolair®.

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, *and leukotriene receptor antagonist*.

Chronic Idiopathic Urticaria

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. Patient is 12 years of age or older; and
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. Patient has documentation of a trial and therapy failure with at least one *preferred* second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one *preferred* first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one *preferred* potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Oral Constipation Agents

Proposed Clinical Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for *oral constipation agents*. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient must have documentation of adequate trials and therapy failures with *both of the following*:
 - a. *Stimulant laxative (senna) plus saline laxative (milk of magnesia)*; and
 - b. *Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose)*.
3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and
4. Patient has one of the following diagnoses:
 - a. A diagnosis of chronic idiopathic constipation (Amitiza® or Linzess™)
 - i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and
 - ii. Patient has two or more of the following symptoms within the last 3 months:
 1. Straining during at least 25% of bowel movements;
 2. Lumpy or hard stools for at least 25% of bowel movements; and
 3. Sensation of incomplete evacuation for at least 25% of bowel movements; and
 - iii. Documentation the patient is not currently taking constipation causing therapies
 - b. A diagnosis of irritable bowel syndrome with constipation (Amitiza® or Linzess™)
 - i. Patient is female (Amitiza® only); and
 - ii. Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following:
 1. Improvement with defecation;
 2. Onset associated with a change in stool frequency; and/or
 3. Onset associated with a change in stool form.
 - c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™ or Relistor®)
 - i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and
 - ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:
 1. Hard to very hard stool consistency;
 2. Moderate to very severe straining; and/or
 3. Having a sensation of incomplete evacuation.
 - iii. *Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.*

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Multiple Sclerosis Agents - Oral

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:

1. A diagnosis of relapsing forms of multiple sclerosis; and
2. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis; *and*
3. *Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.*

For patients initiating therapy with fingolimod (Gilenya™), *a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:*

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure.
2. Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.
3. Patient does not have a baseline QTc interval ≥ 500 ms.
4. Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

1. Patient does not have severe hepatic impairment.
2. A negative pregnancy test for females of childbearing age.
3. Use of a reliable form of contraception for females of childbearing age.
4. Patient is not taking leflunomide.

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.
2. Upon renewal, documentation of an updated CBC.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Additionally, the DUR Commission made the recommendation to: 1) Implement a morphine milligram equivalent (MME) per day limit across the opioid drug class and 2) Implement a quantity limit on Narcan Nasal Spray. Below are the recommended ProDUR edits:

1. Opioids – 90 morphine milligram equivalents (MME) per day across the opioid drug class. Any claims ≥ 90 MME per day will require a prior authorization (criteria currently in development by the DUR Commission)
2. Narcan Nasal Spray – one box (2 doses) per 365 days. Quantities greater than 1 box per 365 days will require a prior authorization (criteria currently in development by the DUR Commission)

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Omalizumab (Xolair); Oral Constipation Agents; and Multiple Sclerosis Agents, Oral as well as the recommended morphine milligram equivalent (MME) per day limit across the opioid drug class and quantity limit on Narcan Nasal Spray.

Sincerely,

A handwritten signature in cursive script that reads "Paula Smith R.Ph.".

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME



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February 2, 2017

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
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Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 1, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Alpha₂ Agonists, Extended-Release; Daclizumab (Zinbryta); and Naloxone Nasal Spray (Narcan Nasal Spray). Additionally, the DUR Commission members made a recommendation to remove the Buprenorphine Transdermal System & Buccal Film prior authorization criteria and move the medications to the Long-Acting Opioids prior authorization criteria. Finally, the DUR Commission members made a recommendation to implement a ProDUR age edit on codeine containing agents. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments that were received from the medical/pharmacy associations in response to a December 14, 2016 letter that was sent to them detailing the proposed criteria for Alpha₂ Agonists, Extended-Release; Daclizumab (Zinbryta); Naloxone Nasal Spray (Narcan Nasal Spray); the removal of the Buprenorphine Transdermal System & Buccal Film prior authorization with the medications being moved to the Long-Acting Opioids prior authorization criteria; as well as the proposed ProDUR age edit on codeine containing agents.

Alpha₂ Agonists, Extended-Release

Proposed Clinical Prior Authorization Criteria (changes noted)

Prior authorization is required for extended-release alpha₂ agonists. Payment will be considered for patients when the following is met:

1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and
2. Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and

3. Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant; ~~and~~
 4. ~~Previous trial and therapy failure at a therapeutic dose with atomoxetine (Strattera®).~~
- The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Daclizumab (Zinbryta)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for daclizumab (Zinbryta). Payment will be considered under the following conditions:

1. Patient has a diagnosis of a relapsing form of multiple sclerosis (MS); and
2. Patient is 18 years of age or older; and
3. Patient has documentation of previous trials and therapy failures with two or more drugs indicated for the treatment of MS; and
4. Patient does not have pre-existing hepatic disease or hepatic impairment (including hepatitis B or C); and
5. Baseline transaminases (ALT, AST) and bilirubin levels are obtained; and
6. Patient does not have an ALT or AST at least 2 times the upper limit of normal (ULN); and
7. Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver, and
8. Patient has been screened for TB and treated for TB if positive; and
9. Daclizumab will be used as monotherapy; and
10. Daclizumab will be dosed as 150 mg once monthly; and
11. Prescriber, patient, and pharmacy are enrolled in the Zinbryta REMS program.
12. The 72-hour emergency supply rule does not apply to daclizumab.
13. Lost or stolen medication replacement requests will not be authorized.

If criteria for coverage are met, an initial authorization will be given for 12 months. Additional authorizations will be considered when documentation of a positive clinical response to daclizumab therapy is provided.

Narcan (Naloxone) Nasal Spray

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for a patient requiring more than 2 doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and
2. Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and
3. The patient is receiving an opioid as verified in pharmacy claims; and
4. Patient has been reeducated on opioid overdose prevention; and

5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and
6. A treatment plan is included documenting a plan to lower the opioid dose.

Buprenorphine Transdermal System & Buccal Film - Removal of current criteria and subject medications to the Long-Acting Opioids criteria

Current Clinical Prior Authorization Criteria for Buprenorphine Transdermal System & Buccal Film (to be removed)

~~Prior authorization is required for Butrans and Belbuca. Payment will be considered when the following conditions are met:~~

- ~~1. Previous trials and therapy failures at a therapeutic dose with two long acting opioids. The preferred trials must allow for adequate dose titration and show use of a short acting narcotic for breakthrough pain.~~
- ~~2. A trial and therapy failure with fentanyl patch at maximum tolerated dose.~~

~~The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.~~

Current Clinical Prior Authorization Criteria for Long-Acting Opioids (buprenorphine transdermal system & buccal film would be subject to criteria below and going forward as updates are made by the DUR Commission)

Prior authorization is required for all non-preferred long-acting opioids. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and
2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and
5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and
6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.

8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered.

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a long-acting opioid is appropriate for this member.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Additionally, the DUR Commission made a recommendation to implement a ProDUR age edit on codeine containing products, restricting its use in children under 18 years of age and removing the 72-hour emergency supply allowance for this age group.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Alpha₂ Agonists, Extended-Release; Daclizumab (Zinbryta); Naloxone Nasal Spray (Narcan Nasal Spray), removal of Buprenorphine Transdermal System & Buccal Film prior authorization with the medications subject to the already established Long-Acting Opioids prior authorization criteria, and the ProDUR age edit on codeine containing agents.

Sincerely,



Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME



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April 7, 2017

Susan L. Parker, R.Ph, Pharm.D.
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, April 5, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Insulin, Pre-Filled Pens; Hepatitis C Treatments; Eteplirsen (Exondys 51); and Lumacaftor/Ivacaftor (Orkambi). Additionally, the DUR Commission members made a recommendation to remove Colchicine from prior authorization. Finally, the DUR Commission members made a recommendation to implement ProDUR quantity limits on select oral and topical GI agents. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments that were received from the medical/pharmacy associations in response to a February 6, 2017 letter that was sent to them detailing the proposed criteria for Insulin, Pre-Filled Pens; Hepatitis C Treatments; Eteplirsen (Exondys51); and Lumacaftor/Ivacaftor (Orkambi); the removal of prior authorization criteria for Colchicine; as well as the proposed ProDUR quantity limits on the oral and topical GI agents.

Insulin, Pre-Filled Pens

Proposed Clinical Prior Authorization Criteria (changes italicized or stricken)

Prior authorization is required for *all* pre-filled insulin pens. *For pre-filled insulin pens where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria: ~~Prior authorization is granted when documentation indicates:~~*

- The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and
- There is no caregiver available to provide assistance, *and*
- Patient does not reside in a long-term care facility; *and*

- *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

For pre-filled insulin pens where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- *Preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and*
- *Non-preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).*
- *Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.*

Hepatitis C Treatments

Proposed Clinical Prior Authorization Criteria (changes italicized)

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older and has a diagnosis of chronic hepatitis C; and
2. Patient has had testing for hepatitis C virus (HCV) genotype; and
3. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
4. *Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and*
5. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and
6. Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:
 - Liver biopsy confirming Metavir score \geq F3; or
 - Transient elastography (FibroScan) score \geq 9.5kPa; or
 - FibroSURE (FibroTest) score \geq 0.58; or
 - APRI score $>$ 1.5; or
 - Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or
 - Physical findings or clinical evidence consistent with cirrhosis; or
 - Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.

7. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
8. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
9. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
10. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and
11. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and
12. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
 - a) Patient is not a pregnant female or male with a pregnant female partner; and
 - b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
 - c) Monthly pregnancy tests will be performed during treatment; and
13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
14. Documentation is provided for patients who are ineligible to receive ~~interferon or~~ ribavirin.
15. Non-FDA approved or non-compensated indicated combination therapy regimens will not be approved.
16. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
17. Lost or stolen medication replacement requests will not be authorized.
18. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Eteplirsen (Exondys 51)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Exondys 51 (eteplirsen). Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing (attach results of genetic testing); and
2. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
3. Patient is currently ambulatory; and
4. A baseline 6-Minute Walk Distance (6MWD) is provided and patient is able to achieve a distance of at least 180 meters while walking independently; and
5. Patient is currently stable on an oral corticosteroid regimen for at least 6 months; and

6. Is dosed based on FDA approved dosing: 30 mg/kg once weekly; and
7. Medication is to be administered by a healthcare professional in member's home by home health or in a long-term care facility.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

When criteria for coverage are met, an initial authorization will be given for 6 months. Requests for continuation of therapy will be considered at 6 month intervals when the following criteria are met:

1. Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent); and
2. An updated 6MWD is provided documenting patient is able to achieve a distance of at least 180 meters.

Lumacaftor/Ivacaftor (Orkambi)

Proposed Clinical Prior Authorization Criteria (changes italicized or stricken)

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient is 6-42 years of age or older; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. ~~Baseline percent predicted forced expiratory volume (ppFEV1) is provided and is greater than or equal to (\geq) 40; and~~
6. Prescriber is a CF specialist or pulmonologist; ~~and~~
7. ~~Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.~~

If the criteria for coverage are met, an initial authorization will be given for 3 months.

Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. ~~Response to therapy is documented by prescriber (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and~~
3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

In addition to the above recommendations for prior authorization, the DUR Commission made a recommendation to remove the Colchicine prior authorization requirement.

Additionally, the DUR Commission made a recommendation to implement ProDUR quantity limits on the following oral and topical GI agents:

Drug	Proposed Quantity Limit
Apriso 0.375 g	4 capsules per day
Azulfidine 500 mg	8 tablets per day
Azulfidine EN-tabs 500 mg	8 tablets per day
Canasa 1000 mg	1 suppository per day
Delzicol 400 mg	6 capsules per day
Dipentum 250 mg	4 capsules per day
Giazo 1.1 g	6 tablets per day
Lialda 1.2 g	4 tablets per day
Pentasa 250 mg	16 capsules per day
Pentasa 500 mg	8 capsules per day
Rowasa, SfRowasa 4 g/60 mL	1680 mL per 28 days
Uceris 9 mg	1 tablet per day

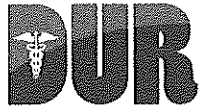
Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Insulin, Pre-Filled Pens; Hepatitis C Treatments; Eteplirsen (Exondys 51); and Lumacaftor/Ivacaftor (Orkambi), removal of Colchicine prior authorization criteria, and the ProDUR quantity limits on select oral and topical GI agents.

Sincerely,



Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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DUR Project Coordinator

June 9, 2017

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, June 7, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for GLP-1 Agonist/Basal Insulin Combinations; Calcifediol; (Ryaldee); Lesinurad (Zurampic); and Sapropterin (Kuvan). Additionally, the DUR Commission members made a recommendation to implement ProDUR quantity limits on Lovenox (enoxaparin) and Fragmin (dalteparin). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an April 11, 2017 letter that was sent to them detailing the proposed criteria for GLP-1 Agonist/Basal Insulin Combinations; Calciferdiol; (Ryaldee); Lesinurad (Zurampic); and Sapropterin (Kuvan), as well as the proposed ProDUR quantity limits on Lovenox (enoxaparin) and Fragmin (dalteparin).

GLP-1 Agonist/Basal Insulin Combinations

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products.

Payment will be considered for patients when the following criteria are met:

1. A diagnosis of type 2 diabetes mellitus; and
2. Patient is 18 years of age or older; and
3. The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and

4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and
5. Will not be used concurrently with prandial insulin; and
6. Clinical rationale is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and
7. Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:
 - a. Soliqua below 15 units or over 60 units, or
 - b. Xultophy persistently below 16 units or over 50 units.

Calcifediol (Rayaldee)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for calcifediol (Rayaldee). Initial requests will be considered for patients when the following criteria are met:

1. Patient is 18 years of age or older; and
2. Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and
3. Patient is not on dialysis; and
4. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past 3 months; and
5. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of 3 months.
6. Initial requests will be considered for a dose of 30 mcg once daily for 3 months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and
2. Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.

Lesinurad (Zurampic)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests will be considered for patients when the following criteria are met:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of hyperuricemia associated with gout; and

3. Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and
4. Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and
5. Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and
6. Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.
 - a. If taking allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min); and
7. Patient does not have a contraindication to therapy including any of the following:
 - a. Severe renal impairment (eCrCl < 30 mL/min),
 - b. End stage renal disease,
 - c. Kidney transplant recipient,
 - d. On dialysis,
 - e. Tumor lysis syndrome, or
 - f. Lesch-Nyhan syndrome.

If criteria for coverage are met, initial requests will be given for 6 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to take medication in combination with a xanthine oxidase inhibitor.
 - a. If allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min)
2. Patient has an eCrCl > 45 mL/min; and
3. Patient does not have a contraindication to therapy including any of the following:
 - a. Severe renal impairment (eCrCl < 30 mL/min),
 - b. End stage renal disease,
 - c. Kidney transplant recipient,
 - d. On dialysis,
 - e. Tumor lysis syndrome, or
 - f. Lesch-Nyhan syndrome.
4. Documentation of a positive clinical response to lesinurad.

The required trials may be overridden when documented evidence is provided that use of the agent(s) would be medically contraindicated.

Sapropterin (Kuvan)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of phenylketonuria (PKU); and
2. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and

3. Patient has a baseline blood Phe level ≥ 360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and
4. Patient's current weight is provided; and
5. Request is for an FDA approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and
6. Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy.

Initial requests will be considered for 1 month to assess response to therapy.

Continuation of therapy will be considered when the following criteria are met:

1. Patient's current weight is provided; and
2. Patient continues on a Phe restricted diet; and
3. For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy.
4. For patients initiated at a dose of 20mg/kg/day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.
5. Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.

Additionally, the DUR Commission made a recommendation to implement ProDUR quantity limits on the following agents (applies to brand and generic):

Drug	Proposed Quantity Limit per 30 Days
Fragmin 2,500 u/0.2 mL; Fragmin 5,000 u/0.2 mL	12 mL
Fragmin 7,500 u/0.3 mL	18 mL
Fragmin 10,000 u/mL; Fragmin 25,000 u/mL	60 mL
Fragmin 12,500 u/0.5 mL	30 mL
Fragmin 15,000 u/0.6 mL	36 mL
Fragmin 18,000 u/0.72 mL	43.2 mL
Lovenox 30 mg/0.3 mL	18 mL
Lovenox 40 mg/0.4 mL	24 mL
Lovenox 60 mg/0.6 mL	36 mL
Lovenox 80 mg/0.8 mL; Lovenox 120 mg/0.8 mL	48 mL
Lovenox 100 mg/mL Lovenox 150 mg/mL	60 mL
Lovenox 300 mg/3mL	180 mL

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for GLP-1 Agonist/Basal Insulin Combinations; Calciferdiol; (Rayaldee); Lesinurad (Zurampic); and Sapropterin (Kuvan); and ProDUR quantity limits on Lovenox (enoxaparin) and Fragmin (dalteparin).

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive, flowing style.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME

Appendix H

Prospective DUR

Prospective DUR SFY17

All recommendations are inclusive of brand and generic agents. The following prospective DUR (ProDUR) edits were recommended to the Department:

- Quantity Limits

Drug/Strength	Proposed Quantity Limit per 30 Days (unless otherwise noted)
Loperamide 2mg tab/cap	120 tablets
Loperamide 1mg/5ml	1200ml
Narcan Nasal Spray	2 doses per 365 days
Apriso 0.375 g	120 capsules
Azulfidine 500mg	240 tablets
Azulfidine EN-tabs 500mg	240 tablets
Canasa 1000mg	30 suppositories
Delzicol 400mg	180 capsules
Dipentum 250mg	120 capsules
Giazo 1.1g	180 tablets
Lialda 1.2g	120 tablets
Pentasa 250mg	480 capsules
Pentasa 500mg	240 capsules
Rowasa, SfRowasa 4g/60ml	1680ml per 28 days
Uceris 9mg	30 tablets
Fragmin 2,500 u/0.2 mL; Fragmin 5,000 u/0.2 mL	12 mL
Fragmin 7,500 u/0.3 mL	18 mL
Fragmin 10,000 u/mL; Fragmin 25,000 u/mL	60 mL
Fragmin 12,500 u/0.5 mL	30 mL
Fragmin 15,000 u/0.6 mL	36 mL
Fragmin 18,000 u/0.72 mL	43.2 mL
Lovenox 30 mg/0.3 mL	18 mL
Lovenox 40 mg/0.4 mL	24 mL
Lovenox 60 mg/0.6 mL	36 mL
Lovenox 80 mg/0.8 mL; Lovenox 120 mg/0.8 mL	48 mL
Lovenox 100 mg/mL Lovenox 150 mg/mL	60 mL
Lovenox 300 mg/3mL	180 mL

- Morphine Milligram Equivalent (MME)
 - ≥ 90 MME/day to require prior authorization (later recommended to start at ≥ 200 MME/day and gradually decrease to goal of < 90 MME/day)
- Age Edit
 - Codeine containing products for members under 18 years of age

Appendix I

Meeting Minutes

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes August 3, 2016

Attendees:

Commission Members
Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Brian Couse, M.D.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
C. David Smith, M.D., IME; Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Laurie Pestel called the meeting to order at 9:35 a.m. at the Learning Resource Center in West Des Moines. The minutes from the June 1, 2016 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Larry Ambroson seconded. The decision was unanimous. Members were asked to complete their annual conflict of interest disclosures. However, they decided to postpone the chairperson and vice-chairperson elections until the October meeting when all members should be present (motion by Kellen Ludvigson, second by Daniel Gillette, with all members in favor). The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update/News Relevant to Medicaid

Pam Smith reviewed her findings on how other states were attempting to control opioid abuse, as well as a report done by Kaiser regarding the most costly Medicaid outpatient drugs (pre-rebate). The top 10 most expensive drugs were: Abilify, Sovaldi, Vyvanse, Harvoni, Truvada, Lantus, methylphenidate er, Atripla, Advair Diskus, and Lantus Solostar. Susan Parker explained why the cost of dispensing fee would be going back down to \$10.02, pending CMS approval. During the initial cost of dispensing survey in 2012, there was a shortage of pharmacists and salaries had escalated, resulting in a higher dispensing fee. The response rate was also higher with the most recent survey, contributing to an average cost of dispensing fee much closer to the national average of \$10.50.

Prevalence Report Summary

This was the first complete set of statistics since the change to managed care, May through June 2016, were discussed, including: cost per user (\$232.02), number of total prescriptions dispensed (a decrease of 91.6% compared to the previous reporting period), average cost per prescription (\$64.63), and generic utilization (84.5%). The total paid amount decreased by 92.3% from the previous reporting period. There were 13,757 unique users, which is 92.1% less than the total for March and April. Lists of the

top 20 therapeutic classes were provided. The highest prescription count continues to come from the SSRI category, with Anticonvulsants still in second place. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Abilify, Strattera, Alphanate/Von Willebrand, Focalin XR, Humalog, Lantus, Advair Diskus, and Adderall XR.

Case Studies

Pam Smith presented 4 case studies. Recommendations by Commissioners from these four examples resulted in annualized total savings of \$2,654.54 pre-rebate (state and federal).

Public Comment

Name	Representing	Drug/Topic
Judy Kelloway	GlaxoSmithKline	Nucala PA
Julie McDavitt	Boehringer-Ingelheim	NOACs - Pradaxa
Steven Woods	Relypsa	Potassium Binders - Veltassa
Nancy Bell	Pfizer	ProDUR edit for MME
Jennifer Stoffel	Janssen	NOACs - Xarelto
Melissa Laurie	Bristol-Myers Squibb	NOACs - Eliquis

Focus Studies

Metoclopramide Utilization Greater than 90 Days: This was a follow-up discussion. Thirty-two (32) of the 95 members identified changed therapy, for an annualized cost savings of \$3,899.12 (state and federal, pre-rebate) as a result of the 222 surveys sent out to prescribers and pharmacies. A total of 97 (43.69%) surveys were returned.

Modafanil Utilization in Members under 21 Years of Age: This was a follow-up discussion. Three of the nine members identified changed therapy, for an annualized cost savings of \$34,836.44 (state and federal, pre-rebate) as a result of the 23 surveys sent out to prescribers and pharmacies. A total of 10 (43.48%) surveys were returned.

Duplicate Antidepressants, Four or More Agents: This was a follow-up discussion. Four of the 11 members identified changed therapy, increasing annualized costs by \$3,702.72 (state and federal, pre-rebate) due to dose consolidation on a more expensive agent. A total of 27 surveys were sent out to prescribers and pharmacies, and 10 (37.04%) of those surveys were returned.

Duplicate SSRIs: This was a follow-up discussion. Three of the 21 members identified changed therapy, for an annualized cost savings of \$607.56 (state and federal, pre-rebate) as a result of the 67 surveys sent out to prescribers and pharmacies. A total of 27 (40.30%) surveys were returned.

Duplicate SNRIs: This was a follow-up discussion. Three of the 15 members identified changed therapy, for an annualized cost savings of \$12,092.48 (state and federal, pre-

rebate) as a result of the 54 surveys sent out to prescribers and pharmacies. A total of 29 (53.70%) surveys were returned.

Duplicate Antidepressants, SSRI plus SNRI: This was a follow-up discussion. Thirty-eight (38) of the 162 members identified changed therapy, for an annualized cost savings of \$5,781.44 (state and federal, pre-rebate) as a result of the 414 surveys sent out to prescribers and pharmacies. A total of 153 (36.96%) surveys were returned.

ProDUR Edits

Morphine Equivalent Dosing (MED) Limits: After discussing the limits that have been implemented in other states, the Commission decided to look into how many members would be affected prior to implementing anything in Iowa. Pam Smith and the MCO representatives will run reports to check the impact at both 90mg and 120mg morphine milligram equivalents per day, along with number of prescriptions with less than and greater than a 15 day supply. It is also likely that a State task force will be developed for this issue, so demonstrated proactive measures are advisable. The first step might be educational releases to providers, to provide adequate warning prior to POS changes and time for tapering. Pam Smith will also check the 2017 Medicare Part D guidelines for comparison.

Loperamide Quantity Limits: The FDA released a Drug Safety Communication in June 2016 regarding serious heart problems with high doses of loperamide, including abuse or misuse of the drug. Based on this warning, a quantity limit of 120 per 30 days was recommended for loperamide 2mg tablet and capsule, and 1200ml per 30 days for loperamide 1mg/5ml solution. Larry Ambrosion motioned to accept the proposed limits, and Kellen Ludvigson and Brett Faine seconded simultaneously. All members were in favor.

Prior Authorization

Lupron Depot Pediatric: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met:

- 1. Patient has a diagnosis of central precocious puberty (CPP); and*
- 2. Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and*
- 3. Patient is currently < 11 years of age for females or < 12 years of age for males; and*
- 4. Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and*
- 5. Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and*
- 6. Baseline evaluations including the following have been conducted and/or evaluated:*

- a. Height and weight measurements; and
- b. Sex steroid (testosterone or estradiol) levels have been obtained; and
- c. Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and
- d. Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and
- e. Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and
- f. Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and
7. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

When criteria for coverage are met, an initial authorization will be given for 6 months.

Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.

Brian Couse motioned to accept the new criteria, and Daniel Gillette seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Lupron Depot Adult: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. Patient is 18 years of age or older; and
2. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
3. Patient has a diagnosis of endometriosis for whom therapy with NSAIDs and at least one preferred 3 month course of a continuous hormonal contraceptive has failed; or
4. Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or
5. Patient has a diagnosis of advanced prostate cancer.

Therapy will be limited as follows:

- *Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.*
- *Uterine leiomyomata – 3 month approval.*
- *Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).*

Brian Couse motioned to accept the new criteria, and Daniel Gillette and Brett Faine seconded simultaneously. Larry Ambroson was out of the room during this vote, but otherwise all members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Short-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting opioids. Payment will be considered under the following conditions:

- 1. Patient has pain severe enough to require opioid treatment; and*
- 2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
- 3. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen or NSAIDs); and*
- 4. Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and*
- 5. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring program website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
- 6. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a short-acting opioid is appropriate for this member.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

Daniel Gillette motioned to accept the new criteria, and Brian Couse seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Buprenorphine/Naloxone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. *Patient has a diagnosis of opioid dependence and is 16 years of age or older: AND*
2. *Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND*
3. *Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND*
4. *A projected treatment plan is provided, including:*
 - *Anticipated induction/stabilization dose,*
 - *Anticipated maintenance dose,*
 - *Expected frequency of office visits, and*
 - *Expected frequency of counseling/psychosocial therapy visits; AND*
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. *Requests for buprenorphine will only be considered for pregnant patients.*

Requests for renewal must include:

- *An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,*
- *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,*
- *Documentation of a current, negative drug screen,*
- *Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.*
- *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

Kellen Ludvigson motioned to accept the new criteria, and Brett Faine seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Topical Acne and Rosacea Products: The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

- 1. Documentation of diagnosis.*
- 2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid for moderate to severe acne.*
- 3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).*
- 4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.*
- 5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.*
- 6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.*
- 7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.*
- 8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

NOACs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is not required for preferred novel oral anticoagulants (NOACs). Prior authorization is required for non-preferred NOACs. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications under the following conditions:

- 1. Patient does not have a mechanical heart valve; and*
- 2. Patient does not have active bleeding; and*
- 3. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA₂DS₂-VASc score ≥ 1 ; and*
- 4. A recent creatinine clearance (CrCl) is provided; and*
- 5. A recent Child-Pugh score is provided; and*
- 6. Patient's current body weight is provided; and*
- 7. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs.*
- 8. For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

In addition to the above PA criteria the DUR Commission made the recommendation to implement the following ProDUR quantity limits on rivaroxaban (Xarelto):

- 10mg tablet – 30 tablets per 30 days*
- 15mg tablets – allow bid dosing for 21 days followed by once daily dosing*
- 20mg tablets – 30 tablets per 30 days*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Patiromer (Veltassa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization (PA) is required for non-preferred potassium binders. Payment will be considered under the following conditions:

- 1. Patient is 18 years of age or older; and*
- 2. Patient has a diagnosis of chronic hyperkalemia; and*

3. Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Mepolizumab (Nucala): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions:

1. Patient is 12 years of age or older; and
2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and
3. Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils of ≥ 300 cells per mcL within 12 months prior to initiation of therapy; and
4. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and
5. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an LABA and LTRA; and
6. A pretreatment forced expiratory volume in 1 second (FEV₁) $< 80\%$ predicted; and
7. Prescriber is an allergist, immunologist, or pulmonologist; and
8. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered if one or more of the following criteria are met:

1. Patient continues to receive therapy with both an ICS, LABA and LTRA; and
2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath, or
3. Patient has experienced a decrease in administration of rescue medication (albuterol); or
4. Patient has experienced a decrease in exacerbation frequency; or
5. Patient has experienced an increase in predicted FEV₁ from the pretreatment baseline.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 1. A disclaimer will be added noting that the Medicaid Statistics for Prescription Claims are for fee for service members only, and do not include those for MCO members when reporting future statistics.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:32, Daniel Gillette motioned to adjourn the meeting and Larry Ambrosion seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, October 5, 2016, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes October 5, 2016

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambrosion, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:33 a.m. at the Learning Resource Center in West Des Moines. The minutes from the August 3, 2016 meeting were reviewed. Kellen Ludvigson motioned to accept them, and Brett Faine seconded. The decision was unanimous. Mark Graber nominated Brett Faine to take over as chairperson, but he declined. Laurie Pestel nominated Mark Graber to remain as chairperson, and Larry Ambrosion seconded. All members were in favor. Kellen Ludvigson nominated Laurie Pestel to remain as vice-chairperson, and Brett Faine and Larry Ambrosion both seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was also reviewed.

IME Pharmacy Update/News Relevant to Medicaid

The P&T Committee will do its annual PDL review in November, and discuss 2017 supplemental rebate contracts at that time. The MCO representatives each provided a summary of their recent prior authorization and claim statistics similar to those provided in the fee-for-service prevalence report summary below. Kellen Ludvigson mentioned an issue he'd had where an MCO member claim required prior authorization when it shouldn't have. Susan Parker asked for more detail so that she could bring it to her monthly meeting, and offered that future similar issues could be sent to her or Pam Smith for follow-up and resolution.

Prevalence Report Summary

Fee-for-service (FFS) statistics from July through August 2016 were discussed, including: cost per user (\$210.45), number of total prescriptions dispensed (a decrease of 24.6% compared to the previous reporting period), average cost per prescription (\$58.78), and generic utilization (86.0%). The total paid amount decreased by 31.7% from the previous reporting period. There were 10,253 unique users, which is 24.7% less than the total for May and June. Lists of the top 20 therapeutic classes were

provided. The highest prescription count continues to come from the SSRI category, with Anticonvulsants still in second place. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Abilify, Strattera, Synagis, Focalin XR, Humalog, Advair Diskus, Onfi, and Latuda.

Public Comment

Name	Representing	Drug/Topic
Jan Foote, ARNP	Blank Children's Hospital	Lupron Depot Ped PA Criteria
Melanie Dumlao	Sanofi Genzyme	Abagio – MS Oral class
Alan Roloff	Biogen Inc.	Tedfidera

Focus Studies

Duplicate Inhaled Corticosteroids: This was a follow-up discussion. Seventeen (17) of the 23 members identified changed therapy, for an annualized cost savings of \$56,392 (state and federal, pre-rebate) as a result of the 63 surveys sent out to prescribers and pharmacies. A total of 22 (34.92%) surveys were returned.

Duplicate Long-Acting Beta-Agonists: This was a follow-up discussion. Seven of the 12 members identified changed therapy, for an annualized cost savings of \$35,371.72 (state and federal, pre-rebate) as a result of the 36 surveys sent out to prescribers and pharmacies. A total of 7 (19.44%) surveys were returned.

ProDUR Edits

Morphine Equivalent Dosing (MED) Limits: As requested at the August meeting, the Commission was provided with reports illustrating the impact to fee-for-service and MCO members if limits were implemented. Kellen Ludvigson motioned to set a limit for 90mg morphine milligram equivalents (MME) per day, for the entire opioid class. Daniel Gillette seconded, and all members in favor. Any claims greater than or equal to 90 MME per day will require a prior authorization. Prior authorization criteria need to be created, possibly 2-tiered in the long-term with differing criteria for 50mg versus 90mg, and potentially requiring a concurrent Narcan prescription for anything higher than 90mg. Pam Smith will look into other states' criteria and see if CMS will share the Medicare Part D PA criteria, and also evaluate the opioids to identify any existing quantity limits that would exceed the 90mg equivalent limit. Kellen Ludvigson also suggested that the PA form require a check of the PMP prior to the prescriber writing the prescription, and that any claim found to have been cashed out for anything greater than an emergency supply would negate the prior authorization.

Narcan Nasal Spray: Kellen Ludvigson motioned to set a limit of one box (2 doses) per 365 days, and Daniel Gillette seconded. All members were in favor. Quantities greater than 1 box per 365 days will require a prior authorization (criteria to be developed by the DUR at a future meeting).

EpiPen: Fee-for-service and MCO pharmacy claims from April through October 2016 will be checked for frequent fills, unique users, and number of fills and results brought to a future meeting. If necessary, this might be an educational initiative.

Prior Authorization

Annual Review of Prior Authorization Criteria: Changes were suggested for the following categories, to be discussed at upcoming meetings:

PA Category	Recommended Changes
Alpha ₂ Agonists, Extended-Release	Remove Strattera trial.
Antidepressants	Check indications to make sure additional diagnoses don't need to be added to #1.
Anti-Diabetics, Non-Insulin Agents	Include language for Incretin Mimetics (reference American Diabetic Association guidelines)
Becaplermin (Regranex®)	Check indications.
Benzodiazepines	Add criteria for use with opioids.
Buprenorphine Transdermal System (Butrans) & Buccal Film (Belbuca)	Move to the Long-Acting Opioids criteria.
Buprenorphine/Naloxone	Reword #6 (Requests for buprenorphine will only be considered for pregnant patients).
Colchicine (Colcrys®)	Re-evaluate if still needed. Amerigroup only had 7 PAs in August and approved them all per Sandy Pranger.
CNS Stimulants and Atomoxetine	Remove all references to ADD as it's no longer a diagnosis and language indicating idiopathic hypersomnia is not a covered diagnosis.
Concurrent IM/PO Antipsychotic Use	Will no longer be needed due to POS duplicate therapy edits being put in place in 2017. Will remove/update once POS edits implemented.
Insulin, Pre-Filled Pens	Possibly change the trial criteria for products that don't have an equivalent preferred agent in a non-pen form or create separate criteria for those agents.
Long-Acting Opioids	Incorporate criteria for benzodiazepines and naloxone.
Lumacaftor/Ivacaftor (Orakmbi™)	Adjust age requirement as now indicated to 6 years of age.
Roflumilast (Daliresp™)	Revise #3 to require an inhaled anticholinergic in combination with an inhaled corticosteroid and long-acting bronchodilator for COPD.

Omalizumab (Xolair): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

- 1. Patient has a diagnosis of moderate to severe persistent asthma for at*

- least one year; and
2. Patient is 6 years of age or older; and
 3. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
 4. Pretreatment IgE level is within the following range:
 - a. Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or
 - b. Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and
 5. Patient's weight is within the following range:
 - a. Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or
 - b. Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and
 6. History of positive skin or RAST test to a perennial aeroallergen; and
 7. Prescriber is an allergist, immunologist, or pulmonologist; and
 8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and
 9. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.
 10. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

Chronic Idiopathic Urticaria

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. Patient is 12 years of age or older; and
3. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
4. Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one

- preferred first-generation antihistamine; and*
- 6. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
 - 7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.*

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Brett Faine motioned to accept the criteria as amended, and Larry Ambroson and Daniel Gillette both seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Oral Constipation Agent: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral constipation agents. Payment will be considered under the following conditions:

- 1. Patient is 18 years of age or older; and*
- 2. Patient must have documentation of adequate trials and therapy failures with both of the following:*
 - a. Stimulant laxative (senna) plus saline laxative (milk of magnesia); and*
 - b. Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose).*
- 3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and*
- 4. Patient has one of the following diagnoses:*
 - a. A diagnosis of chronic idiopathic constipation (Amitiza® or Linzess™)*
 - i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and*
 - ii. Patient has two or more of the following symptoms within the last 3 months:*
 - 1. Straining during at least 25% of bowel movements;*
 - 2. Lumpy or hard stools for at least 25% of bowel movements; and*

3. Sensation of incomplete evacuation for at least 25% of bowel movements; and
- iii. Documentation the patient is not currently taking constipation causing therapies
- b. A diagnosis of irritable bowel syndrome with constipation (Amitiza® or Linzess™)
 - i. Patient is female (Amitiza® only); and
 - ii. Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following:
 1. Improvement with defecation;
 2. Onset associated with a change in stool frequency; and/or
 3. Onset associated with a change in stool form.
- c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™ or Relistor®)
 - i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and
 - ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:
 1. Hard to very hard stool consistency;
 2. Moderate to very severe straining; and/or
 3. Having a sensation of incomplete evacuation.
 - iii. Patient has documentation of an adequate trial and therapy failure with Amitiza® if prior authorization request is for a different oral constipation agent.

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Daniel Gillette motioned to accept the criteria as amended, and Brett Faine and Kellen Ludvigson both seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Multiple Sclerosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:

1. A diagnosis of relapsing forms of multiple sclerosis; and

2. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis; and
3. Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

For patients initiating therapy with fingolimod (Gilenya™), a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure.
2. Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.
3. Patient does not have a baseline QTc interval ≥ 500 ms.
4. Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

1. Patient does not have severe hepatic impairment.
2. A negative pregnancy test for females of childbearing age.
3. Use of a reliable form of contraception for females of childbearing age.
4. Patient is not taking leflunomide.

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.
2. Upon renewal, documentation of an updated CBC.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Daniel Gillette motioned to accept the criteria as amended, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Lupron Depot Pediatric: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of central precocious puberty (CPP); and
2. Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and
3. Patient is currently < 11 years of age for females or < 12 years of age for males; and
4. Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and
5. Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and
6. Baseline evaluations including the following have been conducted and/or evaluated:
 - a. Height and weight measurements; and
 - b. Sex steroid (testosterone or estradiol) levels have been obtained; and
 - c. Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and
 - d. Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and
 - e. Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and
 - f. Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and
7. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

When criteria for coverage are met, an initial authorization will be given for 6 months.

Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.

As this was the second review of these criteria, no motion was necessary. Susan Parker will ask the IME Provider Cost Audit unit to look at the fee schedule for Medical reimbursement of this medication due to the public comment provided. The recommendation will be sent to the Department for consideration.

Lupron Depot Adult: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. Patient is 18 years of age or older; and

2. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
3. Patient has a diagnosis of endometriosis for whom therapy with NSAIDs and at least one preferred 3 month course of a continuous hormonal contraceptive has failed; or
4. Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or
5. Patient has a diagnosis of advanced prostate cancer.

Therapy will be limited as follows:

- Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.
- Uterine leiomyomata – 3 month approval.
- Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Short-Acting Opioids: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all non-preferred short acting opioids. Payment will be considered under the following conditions:

1. Patient has pain severe enough to require opioid treatment; and
2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen or NSAIDs); and
4. Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and
5. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring program website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP

and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and

6. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a short-acting opioid is appropriate for this member.

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Buprenorphine/Naloxone: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of opioid dependence and is 16 years of age or older:
AND
2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND
3. Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND

4. *A projected treatment plan is provided, including:*
 - *Anticipated induction/stabilization dose,*
 - *Anticipated maintenance dose,*
 - *Expected frequency of office visits, and*
 - *Expected frequency of counseling/psychosocial therapy visits; AND*
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. *Requests for buprenorphine will only be considered for pregnant patients.*

Requests for renewal must include:

- *An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,*
- *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,*
- *Documentation of a current, negative drug screen,*
- *Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.*
- *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 1 a second time. The final version will be posted to the DUR website.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:34, Larry Ambrosion motioned to adjourn the meeting and Daniel Gillette seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, December 7, 2016, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes December 7, 2016

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Laurie Pestel, Pharm.D.; Larry Ambroson, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Brian Couse, M.D.; Jason Wilbur, M.D.; and Susan Parker, Pharm.D.

Staff

Pam Smith, R.Ph.

Guests

Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:33 a.m. at the Learning Resource Center in West Des Moines. The minutes from the October 5, 2016 meeting were reviewed. Jason Wilbur motioned to accept them, and Kellen Ludvigson seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was also reviewed, along with the SFY16 Annual DUR Report and a recommendation from the P&T Committee for development of prior authorization criteria for Zinbryta.

IME Pharmacy Update/News Relevant to Medicaid

CMS released the final covered outpatient pharmacy rule that required the states to make changes to their State Plan Amendments effective April 1, 2017. Associated companion rules from the state rules process were released at the end of November 2016, specifying reimbursement methodology, which is already at the required Actual Acquisition Cost (AAC) for Iowa. However, the rules also apply to 340B entities, Federal supply schedule, and nominal price. The rules just make the existing reimbursement methodology official. The only thing that will actually be changing is that Indian Health Services has requested that their pharmacy be reimbursed based on the daily encounter rate set by the Federal government; 100% of funding for this will come from Federal funding. The dispensing fee change from \$11.73 to \$10.02 effective August 1, 2016, is still pending CMS approval. Monthly Iowa Health Link meetings are being held, and all public comments are welcome; one was held on the day of this meeting, December 7, 2016, at the Des Moines Central Library. Pam Smith summarized the updated Medicare/Medicaid drug spending dashboard released by CMS. The MCO representatives each provided a written summary of their recent prior authorization and claim statistics similar to those provided in the fee-for-service prevalence report summary below.

Prevalence Report Summary

Fee-for service statistics from September through October 2016 were discussed, including: cost per user (\$192.72), number of total prescriptions dispensed (an increase of 0.3% compared to the previous reporting period), average cost per prescription (\$52.57), and generic utilization (86.8%). The total paid amount increased by 2.8% from the previous reporting period. There were 7,738 unique users, which is 0.9% more than the total for July and August. Lists of the top 20 therapeutic classes were provided. The highest prescription count continues to come from the SSRI category, with Miscellaneous Narcotics in second place. The top 100 drugs were also reviewed. The ten most expensive medications were: Vyvanse, methylphenidate hcl er, Humalog, Sprycel, Humira Pen, Lantus, Strattera, Latuda, Abilify, and Focalin XR. Pam Smith did make note of the fact that changes to these statistics do not necessarily represent real upward or downward trends, due to the transient nature of the fee-for-service member population as it now stands post MCO transition.

Public Comment

Name	Representing	Drug/Topic
Anthony Pudlo	Iowa Pharmacy Association	Naloxone
Alan Roloff	Biogen	Tecfidera
Nancy Bell	Pfizer	Opiates and Chronic Pain PA
Kerri Hoernemann	Novartis	Entresto
Jan Foote	Blank Children's Hospital	Lupron Depot Ped
Peter Zoob	Vertex	Orkambi

Focus Studies

Hepatitis C Agents: A form will be developed to be faxed to providers 90 days after a member begins therapy, to track progress now that the CPOP program is no longer in operation. A question will be added to this form to ask about hospitalizations, and SVR will be tracked. Information can then be compared to historical studies, or information collected by other states.

ProDUR Edits

EpiPen: As requested at the last meeting, claims from April through October 2016 were checked for frequent fills, unique users, and number of fills. Letters will be sent to the providers of members with three or more fills, to inquire as to the reasoning or circumstances behind multiple fills. The MCOs also agreed to do this, and will bring information regarding responses back to the April 2017 meeting. No Point of Sale (POS) edit will be implemented at this time.

Codeine – Age Edit: An age edit will be implemented in the POS system preventing claims from paying for members less than 18 years of age, and the 72-hour emergency override option will be removed. Daniel Gillette made this motion, Brett Faine seconded, and Jason Wilbur offered a third. All members were in favor.

Prior Authorization

Lumacaftor/ivacaftor (Orkambi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

- 1. Patient is 6 years of age or older; and*
- 2. Has a diagnosis of cystic fibrosis; and*
- 3. Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
- 4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
- 5. Baseline percent predicted forced expiratory volume (ppFEV1) is provided and is greater than or equal to (\geq) 40; and*
- 6. Prescriber is a CF specialist or pulmonologist; and*
- 7. Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

- 1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and*
- 2. Response to therapy is documented by prescriber (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
- 3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.*

Daniel Gillette motioned to accept the criteria as amended, and Larry Ambrosio seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Alpha₂ Agonists, Extended-Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for extended-release alpha₂ agonists. Payment will be considered for patients when the following is met:

- 1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*

2. *Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
3. *Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Daniel Gillette motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Daclizumab (Zinbryta): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for daclizumab (Zinbryta). Payment will be considered under the following conditions:

1. *Patient has a diagnosis of a relapsing form of multiple sclerosis (MS); and*
2. *Patient is 18 years of age or older; and*
3. *Patient has documentation of previous trials and therapy failures with two or more drugs indicated for the treatment of MS; and*
4. *Patient does not have pre-existing hepatic disease or hepatic impairment (including hepatitis B or C); and*
5. *Baseline transaminases (ALT, AST) and bilirubin levels are obtained; and*
6. *Patient does not have an ALT or AST at least 2 times the upper limit of normal (ULN); and*
7. *Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver, and*
8. *Patient has been screened for TB and treated for TB if positive; and*
9. *Daclizumab will be used as monotherapy; and*
10. *Daclizumab will be dosed as 150 mg once monthly; and*
11. *Prescriber, patient, and pharmacy are enrolled in the Zinbryta REMS program.*
12. *The 72-hour emergency supply rule does not apply to daclizumab.*
13. *Lost or stolen medication replacement requests will not be authorized.*

If criteria for coverage are met, an initial authorization will be given for 12 months. Additional authorizations will be considered when documentation of a positive clinical response to daclizumab therapy is provided.

Brett Faine motioned to accept the criteria as listed above, and Brian Couse and Larry Ambrosion both seconded simultaneously. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

High Dose Opioid (≥ 90 MME/day): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day. Patients undergoing active cancer treatment, palliative care, or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code; and
3. The opioid is prescribed by a pain specialist or in consultation with a pain specialist, or oncologist for the treatment of cancer related pain; and
4. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
5. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and
6. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
7. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
8. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
9. Chart notes from a recent pain management visit is included documenting the following:
 - a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
 - b. Treatment goals; and
10. Patient has been informed of the risks of high-dose opioid therapy; and
11. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and

12. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
13. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
14. The requested dosing interval does not exceed the maximum FDA-approved dosing interval; and
15. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
16. Patient has been educated on opioid overdose prevention; and
17. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and
18. Patient will not be using opioids and benzodiazepines concurrently.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 3 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and
3. Patient is not exhibiting warning signs of opioid use disorder; and
4. The benefits of opioids continue to outweigh the risks; and
5. The prescriber has determined the dose cannot be reduced at this time.

Multiple updates were recommended to the above criteria. Pam Smith will revise the criteria as suggested and bring it back to the next meeting for discussion and vote if criteria is sufficient.

Naloxone Nasal Spray: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for a patient requiring more than 2 doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. *Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and*
2. *Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and*
3. *The patient is receiving an opioid as verified in pharmacy claims; and*
4. *Patient has been reeducated on opioid overdose prevention; and*

5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and
6. A treatment plan is included documenting a plan to lower the opioid dose

Jason Wilbur motioned to accept the criteria as amended, and Brian Couse seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Buprenorphine Transdermal System & Buccal Film: Current criteria specific to buprenorphine transdermal system and buccal film will be removed and medications now subject to the current Long-Acting Opioids criteria as listed below:

Prior authorization is required for all non-preferred long-acting opioids. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and
2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and
5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and
6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.
8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered.

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

- 1. Patient has experienced improvement in pain control and level of functioning; and*
- 2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a long-acting opioid is appropriate for this member.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Larry Ambrosion motioned to accept the criteria as amended, and Brian Couse seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Omalizumab (Xolair): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

- 1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and*
- 2. Patient is 6 years of age or older; and*
- 3. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
- 4. Pretreatment IgE level is within the following range:*
 - a. Adults and adolescent patients 12 years of age or older - 30 IU/mL to 700 IU/mL; or*
 - b. Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
- 5. Patient's weight is within the following range:*
 - a. Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; or*
 - b. Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and*
- 6. History of positive skin or RAST test to a perennial aeroallergen; and*
- 7. Prescriber is an allergist, immunologist, or pulmonologist; and*
- 8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND a leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at*

- least three (3) months of therapy; and
9. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.
 10. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of Xolair®.

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, and leukotriene receptor antagonist.

Chronic Idiopathic Urticaria

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. Patient is 12 years of age or older; and
3. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
4. Patient has documentation of a trial and therapy failure with at least one preferred second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Oral Constipation Agent: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for oral constipation agents. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient must have documentation of adequate trials and therapy failures with both of the following:
 - a. Stimulant laxative (senna) plus saline laxative (milk of magnesia); and
 - b. Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose).
3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and
4. Patient has one of the following diagnoses:
 - a. A diagnosis of chronic idiopathic constipation (Amitiza[®] or Linzess[™])
 - i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and
 - ii. Patient has two or more of the following symptoms within the last 3 months:
 1. Straining during at least 25% of bowel movements;
 2. Lumpy or hard stools for at least 25% of bowel movements; and
 3. Sensation of incomplete evacuation for at least 25% of bowel movements; and
 - iii. Documentation the patient is not currently taking constipation causing therapies
 - b. A diagnosis of irritable bowel syndrome with constipation (Amitiza[®] or Linzess[™])
 - i. Patient is female (Amitiza[®] only); and
 - ii. Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following:
 1. Improvement with defecation;
 2. Onset associated with a change in stool frequency; and/or
 3. Onset associated with a change in stool form.
 - c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza[®], Movantik[™] or Relistor[®])
 - i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and
 - ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:
 1. Hard to very hard stool consistency;

2. Moderate to very severe straining; and/or
3. Having a sensation of incomplete evacuation.
- iii. Patient has documentation of an adequate trial and therapy failure with Amitiza[®] if prior authorization request is for a different oral constipation agent.

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Multiple Sclerosis Agents, Oral: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for fingolimod (Gilenya[™]), teriflunomide (Aubagio[®]), or dimethyl fumarate (Tecfidera[™]). Payment will be considered for patients 18 years of age and older under the following conditions:

1. A diagnosis of relapsing forms of multiple sclerosis; and
2. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis; and
3. Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

For patients initiating therapy with fingolimod (Gilenya[™]), a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure.
2. Patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.
3. Patient does not have a baseline QTc interval ≥ 500 ms.
4. Patient is not being treated with Class Ia or Class III anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio[®]), documentation of the following must be provided:

1. Patient does not have severe hepatic impairment.
2. A negative pregnancy test for females of childbearing age.
3. Use of a reliable form of contraception for females of childbearing age.

4. *Patient is not taking leflunomide.*

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

1. *Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.*
2. *Upon renewal, documentation of an updated CBC.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 2. This was the first review and will be brought back to the next meeting for a second review prior to posting to the website.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:35, Daniel Gillette motioned to adjourn the meeting and Larry Ambrosion seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, February 1, 2017, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes February 1, 2017

Attendees:

Commission Members
Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Larry Ambrosion, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Brian Couse, M.D.; Jason Wilbur, M.D.; and Susan Parker, Pharm.D.

Staff
Pam Smith, R.Ph.

Guests
Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:32 a.m. at the Learning Resource Center in West Des Moines. The minutes from the December 7, 2016 meeting were reviewed. Brett Faine motioned to accept them, and Jason Wilbur seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was reviewed.

IME Pharmacy Update/News Relevant to Medicaid

The dispensing fee change from \$11.73 to \$10.02 effective August 1, 2016, is still pending CMS approval. There could be impacts to the program resulting from the current legislative session, but they are as yet unknown. Pam Smith will be attending the ADURS conference at the end of February and hopes to bring new ideas and suggestions back to the April meeting.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a five-minute overview for fee-for service statistics from November through December 2016, including: total amount paid (\$1,536,614), cost per user (\$210.75), and number of total prescriptions dispensed (28,626). There were 7,291 unique users, which is 6.8% less than the total for September and October. There were no large changes on the top 100 pharmacies by prescription count report, given the small FFS population. All ranking changes on the top 100 pharmacies by paid amount report were understandable given the number of members, prescriptions, and drugs dispensed. On the top 100 prescribing providers by prescription count report, the prescribing practices of the top 5 prescribers were all in line with their specialties, with the exception of the top one. She is an OB ARNP, but also sees patients at the Meskwaki clinic. Pam Smith also looked further into the prescribers that had a high prescription per member count. There was nothing out of the ordinary on the top 100 prescribing providers by paid amount report. The top 5 therapeutics classes by paid

amount were: Antipsychotics – Atypicals; Anticonvulsants; Anti-Inflammatories, Non-NSAID; Diabetic – Insulin; and Stimulants – Amphetamines – Long Acting. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics - Miscellaneous, Beta-Lactams/Clavulanate Combos, and Antiasthmatic - Beta - Adrenergics. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Latuda, methylphenidate hcl er, Humalog, Humira Pen, Lantus, Abilify, Strattera, Enbrel Sureclick, and Lamictal. A letter requesting more information has been sent to the provider of the member taking 16 tablets per day of the 25mg strength of Lamictal; claims have been paying as this member has other primary insurance coverage. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, Tramadol 50mg, azithromycin 250mg, Ventolin HFA, and fluoxetine 20mg. Mark Graber noted that the Narcotics were dropping in rank; hopefully that trend will continue.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided a three-minute overview for Amerigroup's statistics from November through December 2016, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count (4 of top 5 are Walgreens), top 100 pharmacies by paid amount (top 5 are all specialty pharmacies), top 100 prescribing providers by prescription count (the provider that moved from 155th to 3rd place changed jobs), and top 100 prescribing providers by paid amount (GI specialist #1). Similar to reports from the last 9 months, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants, Antidiabetics, Antiasthmatic and Bronchodilator Agents, Antipsychotics/Antimanic Agents, and Antivirals. On the top 100 drugs by paid amount report, Synagis jumped 1110.0% to #14, with \$368,480 in expenditures during November and December. Vyvanse was the #1 most expensive medication, followed by methylphenidate er, Humalog, Latuda, and Lantus. The Bi-Monthly Statistics report reflected a fourth quarter/Synagis jump; expenditures totaled \$36,257,769, a 13.2% increase from September and October. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Analgesics – Opioid, and Antihypertensives. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: omeprazole, amoxicillin, lisinopril, and levothyroxine.

United Healthcare Community Plan: Karrie Hansotia spoke for 2 minutes and provided written summaries that included United's statistics from November through December 2016, including: total paid amount, unique users, and cost per user. She noted that not much changed from the September/October reporting period to the November/December period. There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 20 pharmacies by prescription count report, Broadlawn and 4 Walgreens locations made up the top 5. ARJ Infusion Services was the top pharmacy by paid amount. Lists of the top 20 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulin, Antihemophilic Products,

Sympathomimetics, Stimulants – Miscellaneous, and Amphetamines. The top 5 classes by prescription count were: SSRIs, Sympathomimetics, Anticonvulsants – Miscellaneous, Proton Pump Inhibitors, and Opioid Combinations. The most expensive drugs were Novoseven, Vyvanse, Lantus, and methylphenidate, while hydrocodone/apap, amoxicillin, omeprazole, and Lisinopril had the top 4 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a two and a half minute overview for AmeriHealth's statistics from November through December 2016, including: total paid amount (\$35,419,841.48, not much change from the previous reporting period), unique users (116,378), average cost per user (\$304.35), total prescriptions (490,798), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Broadlawns, and Mercy Family had the highest counts), top 100 pharmacies by paid amount (predominantly specialty pharmacies at the top of the list), top 100 prescribing providers by prescription count (some prescribers lower down on the list that moved up quickly in the ranks are being researched), and top 100 prescribing providers by paid amount (top 5 similar to last reporting period). The top 4 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Tx for Attention Deficit-Hyperact (ADHD)/Narcolepsy; and Anticonvulsants. The top 5 therapeutic classes by prescription count were: Anticonvulsants, SSRIs, Antihistamines – 2nd Generation, Proton-Pump Inhibitors, and Narcotic Analgesic and Non-Salicylate Analgesic. The most expensive drugs were Vyvanse, Abilify, methylphenidate er, and Adynovate, whereas hydrocodone-acetaminophen, omeprazole, amoxicillin, lisinopril, and levothyroxine had the highest prescription counts.

Larry Ambrosion asked why there was such a difference in the number of members per MCO plan, so the representatives explained how plans were randomly assigned but still subject to member choice. Pam Smith also noted that the reports had reflected paid claims for Synagis in September & October when claims were not supposed to adjudicate until 11/1/16, and asked the MCOs to investigate those claims. In addition, as all the MCO plans and FFS classified their drug categories a little differently, she wanted to talk with them about that so they could all get a better feel as to true category comparisons.

Public Comment

Name	Representing	Drug/Topic
Pratik Parikh	Sarepta	Exondys 51
Shawn Hansen	Novo Nordisk	Tresiba, Xultify
Tim Starner	University of Iowa	Orkambi

ProDUR Edits

Miscellaneous Quantity Limits: Sandy Pranger from Amerigroup proposed quantity limits for injectable anticoagulants and select GI medications that her company had implemented in other states and run actuarial analysis on the IA Medicaid population, which they estimate would result in \$110,000 in savings in 2017, just for Amerigroup.

Drug	Quantity Limit	Drug	Quantity Limit
Fragmin 10,000 u/ mL, 12,500 u/ 0.5 mL, 15,000 u/0.6 mL, 18,000 u/0.72 mL Syringe	20 mL per 30 days	Lovenox 60 mg/0.6 mL Syringe	16.8 mL per 28 days
Fragmin 2,500 u/0.2 mL; 5,000 u/0.2 mL Syringe	4 mL per 30 days	Lovenox 80 mg/0.8 mL Syringe	22.4 mL per 28 days
Fragmin 25,000 units/ mL Vial	76 mL per 30 days	Lovenox 100 mg/1 mL	28 mL per 28 days
Fragmin 7,500 units/0.3 mL Syringe	6 mL per 30 days	Lovenox 120 mg/0.8 mL Syringe	22.4 mL per 28 days
Lovenox 30 mg/0.3 mL Syringe	8.4 mL per 28 days	Lovenox 150 mg/mL Syringe	28 mL per 28 days
Lovenox 40 mg/0.4 mL Syringe	11.2 mL per 28 days	Lovenox 300 mg/3 mL Vial, Syringe	84 mL per 28 days

The Commission requested additional information to determine how many members would be affected by the limits shown in the table above before implementing them. They said BID dosing needed to be allowed. All MCO and FFS representatives will consult with their respective analysts and bring the requested information back to the April meeting. However, the Commission did motion to accept the suggested quantity limits for the GI agents listed in the table below, as they were in line with the max tolerated doses. Kellen Ludvigson made the motion, while Larry Ambrosio and Brian Couse seconded simultaneously. All members were in favor. The proposed quantity limits below will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Drug	Quantity Limit	Drug	Quantity Limit
Apriso 0.375 g	4 capsules per day	Giazo 1.1 g	6 tablets per day
Azulfidine 500 mg	8 tablets per day	Lialda 1.2 g	4 tablets per day
Azulfidine EN-tabs 500 mg	8 tablets per day	Pentasa 250 mg	16 capsules per day
Canasa 1000 mg	1 suppository per day	Pentasa 500 mg	8 capsules per day
Delzicol 400 mg	6 capsules per day	Rowasa, SfRowasa 4 g/60 mL	1680 mL per 28 days
Dipentum 250 mg	4 capsules per day	Uceris 9 mg	1 tablet per day
Entocort EC 3 mg	3 capsules per day		

Prior Authorization

High Dose Opioid (≥ 90 MME/day): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day. Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and
5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
8. Chart notes from a recent office visit for pain management is included documenting the following:
 - a. Treatment plan — including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
 - b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and

17. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and*
18. *A documented dose reduction is attempted at least annually.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. *High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and*
2. *Patient has not experienced an overdose or other serious adverse event; and*
3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*
5. *The prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*
7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*

Jason Wilbur motioned to accept the criteria as modified, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting. In the future, a POS edit may be needed to block concurrent use of opioids and benzodiazepines. The Commission members inquired if there was still a process to lock in members to pharmacies and prescribers. As the MCO representatives were unsure of the specifics, other than just reporting any issues to Provider Services, they were asked to provide an overview of their Lock In program and contact information for prescribers and pharmacists to recommend members be enrolled in the program at the next meeting.

Insulin, Pre-Filled Pens: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all pre-filled insulin pens. For pre-filled insulin pens where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and
- There is no caregiver available to provide assistance, and
- Patient does not reside in a long-term care facility; and
- For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).

For pre-filled insulin pens where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- Preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and
- Non-preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).
- Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.

Brett Faine motioned to accept the criteria as amended, and Kellen Ludvigson seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

GLP-1 Agonist/Basal Insulin Combinations: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met:

1. A diagnosis of type 2 diabetes mellitus; and
2. Patient is 18 years of age or older; and
3. The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and
4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and
5. Will not be used concurrently with prandial insulin; and

6. *Clinical rationale is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and*
7. *Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:*
 - a. *Soliqua below 15 units or over 60 units, or*
 - b. *Xultophy persistently below 16 units or over 50 units.*

Larry Ambrosio motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Hepatitis C Treatments: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older and has a diagnosis of chronic hepatitis C; and*
2. *Patient has had testing for hepatitis C virus (HCV) genotype; and*
3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
4. *Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and*
5. *Viral load will be submitted by prescriber 12 weeks after completion of therapy; and*
6. *Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:*
 - *Liver biopsy confirming Metavir score \geq F3; or*
 - *Transient elastography (FibroScan) score \geq 9.5kPa; or*
 - *FibroSURE (FibroTest) score \geq 0.58; or*
 - *APRI score $>$ 1.5; or*
 - *Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or*
 - *Physical findings or clinical evidence consistent with cirrhosis; or*
 - *Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.*
7. *Patient's prior treatment history is provided (treatment naïve or treatment*

- experienced); and
8. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
 9. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
 10. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and
 11. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and
 12. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
 - a) Patient is not a pregnant female or male with a pregnant female partner; and
 - b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
 - c) Monthly pregnancy tests will be performed during treatment; and
 13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
 14. Documentation is provided for patients who are ineligible to receive ribavirin.
 15. Non-FDA approved or non-compensated indicated combination therapy regimens will not be approved.
 16. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
 17. Lost or stolen medication replacement requests will not be authorized.
The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Jason Wilbur motioned to accept the criteria as amended, and Kellen Ludvigson seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Eteplirsen (Exondys 51): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Exondys 51 (eteplirsen). Payment will be considered for patients when the following criteria are met:

- 1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing (attach results of genetic testing); and*
- 2. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*
- 3. Patient is currently ambulatory; and*
- 4. A baseline 6-Minute Walk Distance (6MWD) is provided and patient is able to achieve a distance of at least 180 meters while walking independently; and*
- 5. Patient is currently stable on an oral corticosteroid regimen for at least 6 months; and*
- 6. Is dosed based on FDA approved dosing: 30 mg/kg once weekly; and*
- 7. Medication is to be administered by a healthcare professional in member's home by home health or in a long-term care facility.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

When criteria for coverage are met, an initial authorization will be given for 6 months. Requests for continuation of therapy will be considered at 6 month intervals when the following criteria are met:

- 1. Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent); and*
- 2. An updated 6MWD is provided documenting patient is able to achieve a distance of at least 180 meters.*

This medication was recently approved through the FDA's accelerated approval program, based on an increase in dystrophin and skeletal muscle observed in some of the patients treated. However, a clinical benefit has not been established, and continued approval may be contingent upon verification of a clinical benefit confirmed in ongoing trials. The first two trials included just 12 patients, and neither provided evidence of a difference in 6-minute walk distance between active treatment and placebo. Study 3 had 13 patients (12 included in results), whose median increase in dystrophin level at 48 weeks was 0.1%. Cost of this medication would vary by weight of the member, but for a 35kg person it would be \$67,200/month, or just over \$870,000/year. Several members questioned if the state had to pay for this drug as it appeared the state's Medicaid program was essentially paying for research, even if only 4 members in the state would qualify; they felt doing so completely undermines evidence-based medicine. Though other private payers are not covering this medication as they consider it investigational due to lack of established clinical benefit, Medicaid cannot exclude it from coverage. Dr. Smith commented that perhaps even though the trials did not show improvement, patients on this medication might decline at

a slower rate. Under the circumstances, Jason Wilbur motioned to accept the criteria as amended, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting. The IME aims to have criteria for this medication be consistent across both the Medical and Pharmacy programs.

Colchicine: The criteria listed below has been recommended to be removed.

Prior authorization is not required for colchicine (Colcrys®) for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for colchicine (Colcrys®) for the treatment of chronic hyperuricemia/gout prophylaxis or Familial Mediterranean fever. Payment will be considered under the following conditions:

- 1. Chronic hyperuricemia/gout prophylaxis following a trial and therapy failure at a therapeutic dose with allopurinol or probenecid. A quantity limit of sixty (60) tablets per thirty (30) days will be applied, when criteria for coverage are met.*
- 2. Familial Mediterranean fever. A maximum quantity of 120 tablets per thirty (30) days will be applied for this diagnosis.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Amerigroup suggested removing these criteria as the majority of prior authorization requests get approved. A ProDUR edit was recommended to limit usage to a quantity of 60 per 30 days, with any quantity greater than that requiring a PA. Jason Wilbur motioned to remove the criteria and implement the ProDUR edit as recommended, and Brian Couse seconded. All members were in favor. The recommendation to remove PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Lumacaftor/Ivacaftor (Orkambi): The Commission reviewed and voted on the prior authorization criteria as follows:

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiators will not be considered. Payment will be considered for patients when the following criteria are met:

- 1. Patient is 6 years of age or older; and*
- 2. Has a diagnosis of cystic fibrosis; and*
- 3. Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
- 4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
- 5. Prescriber is a CF specialist or pulmonologist; and*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

- 1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and*
- 2. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.*

This was the second review for this medication. After further discussion, the Commission made a recommendation to remove requirements requiring a baseline percent predicted forced expiratory volume (ppFEV1), remove exclusion of patients with *Burkholderia cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus*, and for PA renewals, remove the requirement to provide documentation of a response to therapy. Brett Faine motioned to accept the criteria as amended, and Daniel Gillette seconded. All members were in favor. Due to multiple changes to the criteria, the amended PA criteria will be sent to the medical/pharmacy associations again for comment and brought back to the next DUR meeting.

Alpha₂ Agonists, Extended-Release: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for extended-release alpha₂ agonists. Payment will be considered for patients when the following is met:

- 1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and*
- 2. Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and*
- 3. Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Daclizumab (Zinbryta): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for daclizumab (Zinbryta). Payment will be considered under the following conditions:

- 1. Patient has a diagnosis of a relapsing form of multiple sclerosis (MS); and*
- 2. Patient is 18 years of age or older; and*
- 3. Patient has documentation of previous trials and therapy failures with two or more drugs indicated for the treatment of MS; and*

4. Patient does not have pre-existing hepatic disease or hepatic impairment (including hepatitis B or C); and
5. Baseline transaminases (ALT, AST) and bilirubin levels are obtained; and
6. Patient does not have an ALT or AST at least 2 times the upper limit of normal (ULN); and
7. Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver, and
8. Patient has been screened for TB and treated for TB if positive; and
9. Daclizumab will be used as monotherapy; and
10. Daclizumab will be dosed as 150 mg once monthly; and
11. Prescriber, patient, and pharmacy are enrolled in the Zinbryta REMS program.
12. The 72-hour emergency supply rule does not apply to daclizumab.
13. Lost or stolen medication replacement requests will not be authorized.

If criteria for coverage are met, an initial authorization will be given for 12 months. Additional authorizations will be considered when documentation of a positive clinical response to daclizumab therapy is provided.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Naloxone Nasal Spray: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for a patient requiring more than 2 doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than 2 doses per 365 days will be considered under the following conditions:

1. Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and
2. Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and
3. The patient is receiving an opioid as verified in pharmacy claims; and
4. Patient has been reeducated on opioid overdose prevention; and
5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and
6. A treatment plan is included documenting a plan to lower the opioid dose

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Buprenorphine Transdermal System & Buccal Film: Current criteria will be removed and medications will be subject to the Long-Acting Opioids criteria as listed below:

Prior authorization is required for all non-preferred long-acting opioids. Payment will be considered under the following conditions:

- 1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and*
- 2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
- 3. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and*
- 4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and*
- 5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and*
- 6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
- 7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*
- 8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

- 1. Patient has experienced improvement in pain control and level of functioning; and*
- 2. Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> and has determined continued use of a long-acting opioid is appropriate for this member.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 2. They suggested that a link to the opioid dose calculator would be useful on the www.iadur.org and www.iowamedicaidpdl.com sites.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:45 am, Larry Ambroson motioned to adjourn the meeting and Jason Wilbur seconded. (No closed session was needed.)

The next meeting will be held at 9:30 a.m. on Wednesday, April 5, 2017, at the Iowa Medicaid Enterprise in Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes April 5, 2017

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Laurie Anderson, Pharm.D.; Larry Ambroson, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Brian Couse, M.D.; Jason Wilbur, M.D.; and Susan Parker, Pharm.D.

Staff

Pam Smith, R.Ph.

Guests

Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:35 a.m. at the Iowa Medicaid Enterprise in Des Moines. The minutes from the February 1, 2017 meeting were reviewed. Jason Wilbur motioned to accept them, and Kellen Ludvigson and Brett Faine both seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting was also reviewed.

MCO Lock-In Programs

At the February meeting, the Commission members inquired if there was still a process to lock in members to pharmacies and prescribers. As the MCO representatives were unsure of the specifics, other than just reporting any issues to Provider Services, they were asked to bring that information, specifically the most direct contact options, back to the next meeting. Details are described below.

Amerigroup: Members are assigned to the program if they have 2 providers, 2 pharmacies, 5 controlled substances, and 3 opioids within 45 days. Amerigroup averages about 150 members per month, or 1800 per year, that qualify. Referrals are accepted from anyone, by calling the Provider Services toll-free number. Members, pharmacies, and prescribers will all receive letters before the lock-in goes into effect. Members do have the right to appeal within 10 days if they want to change their lock-in pharmacy.

United Healthcare Community Plan: Members on controlled substances are assigned to the program if they have 9 or more pharmacies per quarter, or 3 or more prescribers as well as 3 or more pharmacies per quarter. Once started, they are locked in for 2 years, at which point their information is reviewed to see if they need to be renewed for another lock-in period or can be released from the program. Members receive

notification letters before the lock-in goes into effect, and are provided a 30-day appeal window. Referrals are accepted by calling Provider Services.

AmeriHealth Caritas Iowa: Program approval has been given, but it has not yet been launched, though tentatively scheduled to go into effect this summer. Members are assigned to the program if 21 years or older with 2 or more prescribers per month, 2 or more qualifying medications per month, or duplicating medications filled. Members can voluntarily restrict themselves if they choose. Referrals are accepted by calling Provider Services, which will transfer the call to a lock-in coordinator. Members, pharmacies, and prescribers will all receive letters before the lock-in goes into effect, and the member is provided a 30-day appeal window. The physician has the right to refuse lock-in assignment, and the pharmacy should, as well. Once started, members are locked in for 2 years, at which point their information is reviewed to see if they need to be renewed for another lock-in period or can be released from the program. Members who lose and gain back eligibility do remain locked in.

Synagis Claims

At the February meeting, Pam Smith noted that the prevalence reports had reflected paid claims for Synagis in the September and October reporting period when claims were not supposed to be allowed to adjudicate until November 1, 2016, and asked that the MCOs could investigate those claims. Each MCO representative explained their findings; most of the claims came from specialty pharmacies who requested overrides to account for shipping to home health care agencies and were not filled early enough to allow for an additional dose beyond the approved 5 within the RSV season. However, given that RSV season usually peaks much later in the season in Iowa (IDPH did not show prevalence until November 20th) and the start date of November 1st was earlier than originally scheduled, Pam Smith and Susan Parker still felt the early overrides weren't necessary.

IME Pharmacy Update/News Relevant to Medicaid

The dispensing fee change from \$11.73 to \$10.02 effective August 1, 2016, has been approved by CMS. An informational letter will go out shortly. Pam Smith reviewed some of the topics that were discussed at the ADURS conference she attended in February.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a four-minute overview for fee-for service statistics from January through February 2017, including: total amount paid (\$1,741,916), cost per user (\$214.31), and number of total prescriptions dispensed (31,081). There were 8,128 unique users, which is 11.4% more than the total for November and December. There were no large changes on the top 100 pharmacies by prescription count report, given the small FFS population. All ranking changes on the top 100 pharmacies by paid amount report were understandable given the number of members, prescriptions, and drugs dispensed. On the top 100 prescribing providers by prescription count report, the prescribing practices of the top 5 prescribers were all in line with their specialties. Pam Smith also looked further into the prescribers that had a high prescription per member

count. There was nothing out of the ordinary on the top 100 prescribing providers by paid amount report. The top 5 therapeutics classes by paid amount were: Anticonvulsants; Antipsychotics – Atypicals; Stimulants – Amphetamines – Long Acting; Anti-Inflammatories, Non-NSAID; and Diabetic – Insulin. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics - Miscellaneous, Beta-Lactams/Clavulanate Combos, and Antipsychotics - Atypicals. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Synagis, Tamiflu, methylphenidate hcl er, Humalog, Latuda, Humira Pen, Onfi, Strattera, and Advair Diskus. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, tramadol 50mg, amoxicillin 400/5ml, azithromycin 250mg, and fluoxetine 20mg. Pam Smith also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that \$98,736,859 was spent in total for 261,785 unique users who had 1,333,399 prescriptions.

MCO Prevalence Report Summary and Updates

United Healthcare Community Plan: Karrie Hansotia spoke for 3 minutes and provided an overview of United's statistics from January through February 2017, including: total paid amount, unique users, and cost per user. She noted that not much changed from the November/December reporting period to the January/February period. The report showed utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns and 4 Walgreens locations made up the top 5. ARJ Infusion Services was the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulins; Adrenergics, Aromatic, Non-Catecholamine; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Antihemophilic Products. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Analgesics, Narcotics; Penicillins; and NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics. The most expensive drugs were Vyvanse, Novoseven, methylphenidate er, Humira Pen, and Humalog, while amoxicillin, hydrocodone/apap, omeprazole, lisinopril, and azithromycin had the top 5 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a six-minute overview for AmeriHealth's statistics from January through February 2017, including: total paid amount (\$35,053,806, not much change from the previous reporting period), unique users (96,878), average cost per user (\$361.83), total prescriptions (499,389), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Mercy Family, and Broadlawns had the highest counts), top 100 pharmacies by paid amount (predominantly specialty pharmacies at the top of the list), top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount (top 4 similar to last reporting period). The top 5 therapeutics classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Anticonvulsants; Adrenergics, Aromatic, Non-Catecholamine; and Tx for Attention Deficit-Hyperactivity (ADHD)/Narcolepsy. The top 5 therapeutic classes

by prescription count were: Anticonvulsants; SSRIs; Penicillins; Proton-Pump Inhibitors; and Beta-Adrenergic Agents, Inhaled, Short Acting. The most expensive drugs were Vyvanse, methylphenidate er, Humalog, Latuda, and Tamiflu, whereas hydrocodone-acetaminophen, loratadine, amoxicillin, cetirizine, and omeprazole had the highest prescription counts.

Amerigroup: Sandy Pranger provided a four-minute overview for Amerigroup's statistics from January through February 2017, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant, Antidiabetics, Antiasthmatic and Bronchodilator Agents, Antipsychotics/Antimanic Agents, and Antivirals. Vyvanse was the most expensive medication, followed by methylphenidate er, Humalog, Latuda, and Humira Pen. The bi-monthly statistics report reflected that expenditures totaled \$36,927,972, a 2.0% increase from November and December. The top five classes by prescription count were: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Analgesics – Opioid. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: amoxicillin, escitalopram, omeprazole, and fluoxetine. Sandy Pranger is checking with report analysts to confirm that reversed claims are not included in the reports; this may account for the discrepancy in totals as compared to reports from the other MCOs.

Oral Public Comment

Name	Representing	Drug/Topic
Lisa Borland	Sarepta	Exondys 51
Charles Tyler	Marathon Pharmaceuticals	Emflaza
Jason Luek	Novo Nordisk	Xultophy

The Commission also reviewed written public comment as part of their meeting materials. The following written comments were reviewed:

- The Iowa Pharmacy Association (IPA) provided comments on: High Dose Opioids; Insulin-Prefilled Pens; GLP-1 Agonist/Basal Insulin Combinations; Hepatitis C Treatments; Eteplirsen (Exondys 51); removal of Colchicine PA criteria; and Lumacaftor/Ivacaftor (Orkambi).
- A letter from the University of Iowa Stead Family Children's Hospital regarding proposed Exondys 51 PA criteria.
- A letter from the Cystic Fibrosis Foundation supporting the revisions to the PA criteria for lumacaftor/ivacaftor.

ProDUR Edits

Injectable Anticoagulant Quantity Limits: At the February meeting, Sandy Pranger from Amerigroup proposed quantity limits that her company had implemented in other states and run actuarial analysis on for the IA Medicaid population, which they think would result in \$110,000 in savings in 2017, just for Amerigroup.

Drug	Quantity Limit	Drug	Quantity Limit
Fragmin 10,000 u/ mL, 12,500 u/ 0.5 mL, 15,000 u/0.6 mL, 18,000 u/0.72 mL Syringe	20 mL per 30 days	Lovenox 60 mg/0.6 mL Syringe	16.8 mL per 28 days
Fragmin 2,500 u/0.2 mL; 5,000 u/0.2 mL Syringe	4 mL per 30 days	Lovenox 80 mg/0.8 mL Syringe	22.4 mL per 28 days
Fragmin 25,000 units/ mL Vial	76 mL per 30 days	Lovenox 100 mg/1 mL	28 mL per 28 days
Fragmin 7,500 units/0.3 mL Syringe	6 mL per 30 days	Lovenox 120 mg/0.8 mL Syringe	22.4 mL per 28 days
Lovenox 30 mg/0.3 mL Syringe	8.4 mL per 28 days	Lovenox 150 mg/mL Syringe	28 mL per 28 days
Lovenox 40 mg/0.4 mL Syringe	11.2 mL per 28 days	Lovenox 300 mg/3 mL Vial, Syringe	84 mL per 28 days

The Commission wanted to see how many members would be affected by the limits shown in the table above before implementing them (with an allowance for BID dosing), so all the MCO and FFS representatives consulted with their respective analysts and brought back the requested information as follows: AmeriGroup with 57 members, United Healthcare with 71, AmeriHealth with 50 or more per month (also found incorrect quantities billed resulting in overpayment), and FFS with 13 members. Kellen Ludvigson motioned to recommended placing quantity limits on the above agents, after doubling them to allow for BID dosing. Daniel Gillette and Jason Wilbur both seconded, and all members were in agreement. The recommended quantity limits will be sent out for public comment and brought back to the next meeting.

Miscellaneous Quantity Limits: New quantity limits for the oral agents listed in the table below will be implemented. No motion was necessary as this was the second review. The recommendation will be sent to the Department for consideration.

Drug	Quantity Limit	Drug	Quantity Limit
Apriso 0.375 g	4 capsules per day	Giazo 1.1 g	6 tablets per day
Azulfidine 500 mg	8 tablets per day	Lialda 1.2 g	4 tablets per day
Azulfidine EN-tabs 500 mg	8 tablets per day	Pentasa 250 mg	16 capsules per day
Canasa 1000 mg	1 suppository per day	Pentasa 500 mg	8 capsules per day
Delzicol 400 mg	6 capsules per day	Rowasa, SfRowasa 4 g/60 mL	1680 mL per 28 days
Dipentum 250 mg	4 capsules per day	Uceris 9 mg	1 tablet per day
Entocort EC 3 mg	3 capsules per day		

EpiPen: As requested at the December meeting, letters were sent to the providers of members with three or more fills from April through October 2016, to inquire as to the reasoning or circumstances behind multiple fills. Amerigroup had 37 claims and contacted all prescribers; many were unaware members were receiving that much.

United Healthcare had 26 claims and were able to reach out to 23 prescribers, though 21 of the prescribers had no plans to contact the members. AmeriHealth had 19 claims and mailed out surveys; 8 surveys were returned with auto-filling listed as the issue in at least 3 instances. No Point of Sale (POS) quantity limit or edit will be implemented at this time but claims should continue to be monitored. Kellen Ludvigson also suggested calling pharmacies to try to prevent auto-filling, as the MCOs had targeted prescribers.

Prior Authorization

Deflazacort (Emflaza):

Prior authorization is required for Emflaza (deflazacort). Payment will be considered for patients when the following criteria are met:

- 1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and*
- 2. Patient is within the FDA labeled age; and*
- 3. Patient experienced onset of weakness before 5 years of age; and*
- 4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*
- 5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain ($> X\%$ of baseline bodyweight) with prednisone at a therapeutic dose; and*
- 6. Is dosed based on FDA approved dosing.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

The Commission felt BMI or percentile on a growth chart might be a better reflection of weight gain as opposed to a certain (as yet undetermined) percentage of baseline bodyweight. The topic was tabled to allow Pam Smith to seek input from a specialist that treats DMD.

Calcifediol (Ryaldee): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for calcifediol (Ryaldee). Initial requests will be considered for patients when the following criteria are met:

- 1. Patient is 18 years of age or older; and*
- 2. Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and*
- 3. Patient is not on dialysis; and*
- 4. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past 3 months; and*
- 5. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of 3 months.*
- 6. Initial requests will be considered for a dose of 30 mcg once daily for 3 months.*

Continuation of therapy will be considered when the following criteria are met:

- 1. Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and*
- 2. Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.*

Brett Faine motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Lesinurad (Zurampic): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests will be considered for patients when the following criteria are met:

- 1. Patient is 18 years of age or older; and*
- 2. Patient has a diagnosis of hyperuricemia associated with gout; and*
- 3. Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and*
- 4. Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and*
- 5. Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and*
- 6. Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.*
 - a. If taking allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min); and*
- 7. Patient does not have a contraindication to therapy including any of the following:*
 - a. Severe renal impairment (eCrCl < 30 mL/min),*
 - b. End stage renal disease,*
 - c. Kidney transplant recipient,*
 - d. On dialysis,*
 - e. Tumor lysis syndrome, or*
 - f. Lesch-Nyhan syndrome.*

If criteria for coverage are met, initial requests will be given for 6 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to take medication in combination with a xanthine oxidase inhibitor.
 - a. If allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min)
2. Patient has an eCrCl > 45 mL/min; and
3. Patient does not have a contraindication to therapy including any of the following:
 - a. Severe renal impairment (eCrCl < 30 mL/min),
 - b. End stage renal disease,
 - c. Kidney transplant recipient,
 - d. On dialysis,
 - e. Tumor lysis syndrome, or
 - f. Lesch-Nyhan syndrome.
4. Documentation of a positive clinical response to lesinurad.

The required trials may be overridden when documented evidence is provided that use of the agent(s) would be medically contraindicated.

Brian Couse motioned to accept the criteria as amended, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Sapropterin (Kuvan): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of phenylketonuria (PKU); and
2. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and
3. Patient has a baseline blood Phe level ≥ 360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and
4. Patient's current weight is provided; and
5. Request is for an FDA approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and
6. Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy.

Initial requests will be considered for 1 month to assess response to therapy.

Continuation of therapy will be considered when the following criteria are met:

1. Patient's current weight is provided; and

2. *Patient continues on a Phe restricted diet; and*
3. *For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy.*
4. *For patients initiated at a dose of 20mg/kg/per day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.*
5. *Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.*

Daniel Gillette motioned to accept the criteria as amended, and Jason Wilbur seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

High Dose Opioid (≥ 90 MME/day): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day. Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. *Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and*
2. *Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and*
3. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
4. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and*
5. *There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and*
6. *Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and*
7. *Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and*

8. *Chart notes from a recent office visit for pain management is included documenting the following:*
 - a. *Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and*
 - b. *Treatment goals; and*
9. *Patient has been informed of the risks of high-dose opioid therapy; and*
10. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and*
11. *The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and*
12. *A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and*
13. *The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and*
14. *Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and*
15. *Patient has been educated on opioid overdose prevention; and*
16. *Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and*
17. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and*
18. *A documented dose reduction is attempted at least annually.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. *High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and*
2. *Patient has not experienced an overdose or other serious adverse event; and*
3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*
5. *The prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*

7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*

Given the additional burden this will create for the MCOs, the Commission agreed to initially only apply the criteria for new starts, and let existing users continue on their existing regimens for now, potentially addressing them in a future DUR focus study. They also suggested letters and calls to providers and members along with the customary informational letter. Pam Smith and the MCO representatives will look into how many members and providers will be impacted and bring those numbers back to the next meeting. Laurie Pestel asked if data could be examined to identify those taking benzodiazepines concurrently. Additionally, it was suggested that bullets 14-18 be copied to the refill criteria section. Pam Smith will revise the criteria and bring it back to the next meeting.

Insulin, Pre-Filled Pens: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for all pre-filled insulin pens. For pre-filled insulin pens where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- *The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and*
- *There is no caregiver available to provide assistance, and*
- *Patient does not reside in a long-term care facility; and*
- *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

For pre-filled insulin pens where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- *Preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and*
- *Non-preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).*
- *Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

GLP-1 Agonist/Basal Insulin Combinations: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met:

- 1. A diagnosis of type 2 diabetes mellitus; and*
- 2. Patient is 18 years of age or older; and*
- 3. The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and*
- 4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and*
- 5. Will not be used concurrently with prandial insulin; and*
- 6. Clinical rationale is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and*
- 7. Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:*
 - a. Soliqua below 15 units or over 60 units, or*
 - b. Xultophy persistently below 16 units or over 50 units.*

As this was the second review of these criteria, no motion was necessary. Midway through the discussion, a request was made to revisit the High Dose Opioids criteria. Since the DUR Commission did not have the opportunity to further discuss the proposed criteria, this item will be brought back to the June 2017 DUR meeting to allow Commissioners the opportunity for further discussion, if needed, prior to making the recommendation to the Department.

Hepatitis C Treatments: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

- 1. Patient is 18 years of age or older and has a diagnosis of chronic hepatitis C; and*
- 2. Patient has had testing for hepatitis C virus (HCV) genotype; and*
- 3. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and*
- 4. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV*

- therapy or before HCV therapy is started; and*
5. *Viral load will be submitted by prescriber 12 weeks after completion of therapy; and*
 6. *Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:*
 - *Liver biopsy confirming Metavir score \geq F3; or*
 - *Transient elastography (FibroScan) score \geq 9.5kPa; or*
 - *FibroSURE (FibroTest) score \geq 0.58; or*
 - *APRI score > 1.5 ; or*
 - *Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or*
 - *Physical findings or clinical evidence consistent with cirrhosis; or*
 - *Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.*
 7. *Patient's prior treatment history is provided (treatment naïve or treatment experienced); and*
 8. *If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and*
 9. *Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and*
 10. *For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30 ml/min) or end stage renal disease requiring hemodialysis; and*
 11. *HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and*
 12. *For patients on a regimen containing ribavirin, the following must be documented on the PA form:*
 - a) *Patient is not a pregnant female or male with a pregnant female partner; and*
 - b) *Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and*
 - c) *Monthly pregnancy tests will be performed during treatment; and*
 13. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
 14. *Documentation is provided for patients who are ineligible to receive ribavirin.*
 15. *Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.*
 16. *If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the*

- remainder of therapy needed, based on length of therapy for the particular treatment.*
- 17. Lost or stolen medication replacement requests will not be authorized.*
 - 18. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

The Commission is also interested in potentially adjusting the criteria to include members with a Metavir score of 2 or greater fibrosis now that many members in the more advanced stages have received treatment. Criteria will be brought back to a future meeting to discuss changes.

Eteplirsen (Exondys 51): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Exondys 51 (eteplirsen). Payment will be considered for patients when the following criteria are met:

- 1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing (attach results of genetic testing); and*
- 2. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and*
- 3. Patient is currently ambulatory; and*
- 4. A baseline 6-Minute Walk Distance (6MWD) is provided and patient is able to achieve a distance of at least 180 meters while walking independently; and*
- 5. Patient is currently stable on an oral corticosteroid regimen for at least 6 months; and*
- 6. Is dosed based on FDA approved dosing: 30 mg/kg once weekly; and*
- 7. Medication is to be administered by a healthcare professional in member's home by home health or in a long-term care facility.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

When criteria for coverage are met, an initial authorization will be given for 6 months. Requests for continuation of therapy will be considered at 6 month intervals when the following criteria are met:

- 1. Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent); and*
- 2. An updated 6MWD is provided documenting patient is able to achieve a distance of at least 180 meters.*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Colchicine: The criteria listed below is recommended to be removed.

Prior authorization is not required for colchicine (Colcrys®) for the treatment of acute gout for three (3) tablets per 60-day period. Prior authorization is required for colchicine (Colcrys®) for the treatment of chronic hyperuricemia/gout prophylaxis or Familial Mediterranean fever. Payment will be considered under the following conditions:

- 1. Chronic hyperuricemia/gout prophylaxis following a trial and therapy failure at a therapeutic dose with allopurinol or probenecid. A quantity limit of sixty (60) tablets per thirty (30) days will be applied, when criteria for coverage are met.*
- 2. Familial Mediterranean fever. A maximum quantity of 120 tablets per thirty (30) days will be applied for this diagnosis.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Lumacaftor/ivacaftor (Orkambi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

- 1. Patient is 6 years of age or older; and*
- 2. Has a diagnosis of cystic fibrosis; and*
- 3. Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and*
- 4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and*
- 5. Prescriber is a CF specialist or pulmonologist; and*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

- 1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and*
- 2. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.*

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members reviewed the draft for DUR Digest Volume 29, Number 3. It will be brought back to the next meeting for a second review.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

Articles of Interest:

First- and Second-Generation Antipsychotics in Children and Young Adults: Systematic Review Update; found at

<https://www.effectivehealthcare.ahrq.gov/ehc/products/615/2437/antipsychotics-children-update-report-170316.pdf>

Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; found at

<http://www.nejm.org/doi/full/10.1056/NEJMoa1615664#t=article>

After reviewing the articles provided, the Commission decided to check back on claims data in six months to see if the new age edits already implemented had an effect on antipsychotic use in children and young adults. As evolocumab has shown no effect on mortality in patients with cardiovascular disease, they did not want to change that criteria at this time, either.

At 12:22, Brett Faine motioned to adjourn the meeting and Daniel Gillette seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, June 7, 2017, at the Learning Resource Center in West Des Moines.

Iowa Medicaid Drug Utilization Review Commission

Meeting Minutes June 7, 2017

Attendees:

Commission Members

Mark Graber, M.D., FACEP; Larry Ambroson, R.Ph.; Daniel Gillette, M.D.; Brett Faine, Pharm.D.; Kellen Ludvigson, Pharm.D.; Brian Couse, M.D.; and Susan Parker, Pharm.D.

Staff

Pam Smith, R.Ph.

Guests

Erin Halverson, R.Ph., IME; Melissa Biddle, IME; Sandy Pranger, R.Ph., Amerigroup; Jennifer Schonhorst, Pharm.D., AmeriHealth Caritas; and Karrie Hansotia, United Healthcare Plan of the River Valley.

Welcome & Introductions

Mark Graber called the meeting to order at 9:37 a.m. at the Learning Resource Center in West Des Moines. The minutes from the April 5, 2017 meeting were reviewed. Daniel Gillette motioned to accept them, Brian Couse seconded. The decision was unanimous. The recommendation letter sent to DHS after the last meeting, a recommendation letter from the P&T Committee regarding development of PA criteria for Exondys 51, and a letter from Advocates for Opioid Recovery were also reviewed. There will be no changes to buprenorphine/naloxone prior authorization criteria and quantity limits at this time, but they will be reviewed at a future meeting.

IME Pharmacy Update

The Iowa legislature made a change to the P&T Committee and DUR Commission code language, which states: "When making recommendations or determinations regarding beneficiary access to drugs and biological products for rare diseases as defined in the Federal Orphan Drug Act of 1983, publication number 97-414, and drugs and biological products that are genetically targeted, the committee shall request and consider information from individuals who possess scientific or medical training with respect to the drug, biological product, or rare disease." The IME is currently working on a new process for the committees, which will most likely result in drug discussions being delayed. Information will be brought to the committees once finalized, and it will also be provided on the website. The legislature is also requiring DHS to review the use of step therapy protocols and the application of step therapy override exceptions in the Iowa Medicaid program. In the review the Department may consider the use of step therapy protocols and the application of step therapy override exceptions as provided in Chapter 514F.7 if enacted by 2017 Iowa Acts House File 233 and the potential for improving the quality of life of Medicaid members and increasing efficiencies in the Medicaid program. The Department shall report findings of the review and recommendations to the individuals designated in this Act for submission of reports by November 15, 2017.

514F.7 has to do with those providers that are under the jurisdiction of the insurance commissioner, and Medicaid is not. House File 233 was enacted as part of the legislation under the insurance division section, and defines step therapy as a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular covered person, are covered under a pharmacy or medical benefit by a health carrier, health benefit plan, or utilization review organization, including self-administered drugs and drugs administered by a health care professional. Both the IME Pharmacy and Medical benefits will be reviewing this. From a Pharmacy benefit perspective, it would impact the sequence requiring someone to try a preferred medication before allowing them to take a non-preferred medication, as well as some of the established criteria in the PA criteria. IME will be looking at the current process versus the process that is defined in the House File to see if any changes or improvements need to be made, or if requirements are already being met. IME has a relatively transparent process for how it does things, compared to what some of the other insurers do. Any resulting recommended changes will be brought back to the Commission at the next meeting in August. Pam Smith presented Brian Couse and Larry Ambroson with letters and certificates signed by the Medicaid Director in thanks for their service, as this was their last meeting.

Fee-for-Service Prevalence Report Summary

Pam Smith provided a three-and-a-half-minute overview for fee-for service statistics from March through April 2017, including: total amount paid (\$1,618,380), cost per user (\$216.19), and number of total prescriptions dispensed (29,207). There were 7,486 unique users, which is 8.8% less than the total for January and February. There were no large changes on the top 100 pharmacies by prescription count report, given the small FFS population. All ranking changes on the top 100 pharmacies by paid amount report were understandable given the number of members, prescriptions, and drugs dispensed. On the top 100 prescribing providers by prescription count report, the prescribing practices of the top 5 prescribers were all in line with their specialties. Pam Smith also looked further into the prescribers that had a high prescription per member count. There was nothing out of the ordinary on the top 100 prescribing providers by paid amount report. The top 5 therapeutics classes by paid amount were: Antipsychotics – Atypicals; Anticonvulsants; Anti-Inflammatories, Non-NSAID; Stimulants – Amphetamines – Long Acting; and Diabetic – Insulin. The highest prescription count continues to come from the SSRI category, with Anticonvulsants in second place, followed by: Narcotics - Miscellaneous, Antipsychotics – Atypicals, and Beta-Lactams/Clavulanate Combos. The top 100 drugs were also reviewed, by paid amount and prescription count. The ten most expensive medications were: Vyvanse, Latuda, methylphenidate hcl er, Strattera, Humalog, Humira Pen, Lantus, Advair Diskus, Norditropin Flexpro, and Onfi. The five drugs with the highest prescription count were: hydrocodone/apap 5-325mg, Tramadol 50mg, fluoxetine 20mg, clonidine 0.1mg, and Ventolin HFA. Pam Smith also created a report that compared the FFS stats above with those from each MCO below. Its side-by-side statistics showed that \$98,475,984 was spent in total for 250,777 unique users who had 1,306,567 prescriptions.

MCO Prevalence Report Summary and Updates

Amerigroup: Sandy Pranger provided a two-and-a-half-minute overview for Amerigroup's statistics from March through April 2017, including: a breakdown of utilization by age and gender, top 100 pharmacies by prescription count, top 100 pharmacies by paid amount, top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount. Similar to previous reports, the top 5 therapeutics classes by paid amount were: ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant, Antidiabetics, Antiasthmatic and Bronchodilator Agents, Antipsychotics/Antimanic Agents, and Antivirals. Vyvanse was the #1 most expensive medication, followed by methylphenidate er, Latuda, Humira Pen, and Humalog. The Bi-Monthly Statistics report reflected that expenditures totaled \$35,408,088, a 3.5% decrease from January and February. These were the top five classes by prescription count: Antidepressants, Antiasthmatic and Bronchodilator Agents, Anticonvulsants, Antihypertensives, and Analgesics – Opioid. Hydrocodone-acetaminophen has been the drug with the highest prescription count since April 1, 2016, followed by: escitalopram, omeprazole, and Ventolin HFA. After the last meeting, Sandy Pranger checked with report analysts to confirm that reversed claims are not included in the reports. They had been previously included, but the issue has now been corrected.

United Healthcare Community Plan: Karrie Hansotia spoke for 3 and a half minutes and provided written summaries that included United's statistics from March through April 2017, including: total paid amount, unique users, and cost per user. She noted that not much changed from the January/February reporting period to the March/April period. There was also a handout showing utilization by age and gender; females age 19-64 had the highest utilization. On the top 100 pharmacies by prescription count report, Broadlawns and 4 Walgreens locations made up the top 5. ARJ Infusion Services was the top pharmacy by paid amount. Lists of the top 100 prescribers by prescription count and paid amount were provided. The top 5 therapeutic classes by paid amount were: Insulins; Antihemophilic Factors; Adrenergics, Aromatic, Non-Catecholamine; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Tx for Attention Deficit-Hyperactivity (ADHD)/Narcolepsy. The top 5 classes by prescription count were: SSRIs; Anticonvulsants; Analgesics, Narcotics; Penicillins; and NSAIDs, Cyclooxygenase Inhibitor-Type Analgesics. The most expensive drugs were Novoseven RT, Vyvanse, methylphenidate er, Harvoni, Humira Pen, and Humalog, while hydrocodone/apap, amoxicillin, omeprazole, Lisinopril, and levothyroxine sodium had the top 5 prescription counts.

AmeriHealth Caritas Iowa: Jennifer Schonhorst provided a four-minute overview for AmeriHealth's statistics from March through April 2017, including: total paid amount (\$35,111,886 - not much change from the previous reporting period), unique users (92,364), average cost per user (\$380.15), total prescriptions (495,639), utilization by age and gender (age 19-64 category highest for both genders), top 100 pharmacies by prescription count (Walgreens, Mercy Family, and Broadlawns had the highest counts), top 100 pharmacies by paid amount (predominantly specialty pharmacies at the top of the list), top 100 prescribing providers by prescription count, and top 100 prescribing providers by paid amount (top 4 similar to last reporting period). The top 5 therapeutics

classes by paid amount were: Insulins; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; Adrenergics, Aromatic, Non-Catecholamine; Anticonvulsants; and Tx for Attention Deficit-Hyperactivity (ADHD)/Narcolepsy. The top 5 therapeutic classes by prescription count were: Anticonvulsants; SSRIs; Proton-Pump Inhibitors; Antipsychotic, Atypical, Dopamine, Serotonin Antagonist; and Penicillins. The most expensive drugs were Vyvanse, methylphenidate er, Latuda, Humalog, and Lantus, whereas omeprazole, hydrocodone-acetaminophen, amoxicillin, lisinopril, and levothyroxine sodium had the highest prescription counts.

Public Comment

In addition to the written public comments provided to Commission members, they heard oral public comments from the speakers listed below.

Name	Representing	Drug/Topic
Robert Lyon	Genentech	Xolair
Greg Kitchens	Artia Solutions/PTC Therapeutics	Emflaza
Kerri Hoernemann	Novartis	Entresto
Nancy Bell	Pfizer	Eucrisa
Anthony Pudlo	Iowa Pharmacy Association	AMA principles for PA
Jason Lurk	Novo Nordisk	Xultophy 100/3.6

Retrospective Claims Analysis

Concomitant Use of Benzodiazepines and Opioids: The Commission wanted to know how many providers would be affected, and what percentage of all opioid users had concomitant use with a benzodiazepine. They suggested including patient information on informational letters to improve rate of response and impact. Pam Smith with work with the MCOs to define parameters and letter substance and bring more information back to the next meeting.

ProDUR Edits

Injectable Anticoagulant Quantity Limits: After discussion at the April 5, 2017 DUR meeting, a recommendation was made to implement ProDUR quantity limits on the injectable anticoagulants listed below, allowing for twice daily dosing to prevent incorrect quantities billed or excessive dosing. As this was the second review, no motion was necessary. The recommendation will be sent to the Department for consideration.

Drug	Proposed Quantity Limit per 30 Days
Fragmin 2,500 u/0.2 mL; Fragmin 5,000 u/0.2 mL	12 mL
Fragmin 7,500 u/0.3 mL	18 mL
Fragmin 10,000 u/mL; Fragmin 25,000 u/mL	60 mL

Fragmin 12,500 u/0.5 mL	30 mL
Fragmin 15,000 u/0.6 mL	36 mL
Fragmin 18,000 u/0.72 mL	43.2 mL
Lovenox 30 mg/0.3 mL	18 mL
Lovenox 40 mg/0.4 mL	24 mL
Lovenox 60 mg/0.6 mL	36 mL
Lovenox 80 mg/0.8 mL; Lovenox 120 mg/0.8 mL	48 mL
Lovenox 100 mg/mL Lovenox 150 mg/mL	60 mL
Lovenox 300 mg/3mL	180 mL

Prior Authorization

Prior Authorization Process:

- i. **American Medical Association Prior Authorization and Utilization Management Reform Principles:** After reviewing the document provided at <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf>, the Commission agreed these were good points to keep in mind when creating criteria, but most of them were already being followed. Number 19 is not possible with the current IME systems, as provider specialty designation is only optional with enrollment. Pam Smith will look into how other states identify outlying prescribers.
- ii. **Iowa House File 233 – Step Therapy Protocols for Prescription Drugs:** Commission members were provided a copy of House File 233 that Susan Parker discussed in the IME Updates section above. Pam Smith believes the language found in section 3b would be most application to the DUR Commission. It states “a step therapy override exception shall be approved by the health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:
 1. The prescription drug required under the step therapy protocol is contraindicated pursuant to the drug manufacturer’s prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:
 - (a) Cause an adverse reaction to a covered person.
 - (b) Decrease the ability of a covered person to achieve or maintain reasonable functional ability in performing daily activities.
 - (c) Cause physical or mental harm to a covered person.
 2. The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person’s adherence to or compliance with the covered person’s individual plan of care, and any of the following:
 - (a) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer’s prescribing

information for the drug.

(b) The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals.

(c) The covered person's documented experience with the prescription drug regimen.

3. The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the covered person's health care professional due to lack of effectiveness.
4. The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while under the covered person's current or previous health benefit plan. This subparagraph shall not be construed to encourage the use of a pharmaceutical sample for the sole purpose of meeting the requirements for a step therapy override exception.

Pam Smith noted that the IME already gives a lot of consideration for the situations listed above through prior authorization, specifically to b1 and b3, when proper documentation is provided. b2 and b4 could also be considered if valid clinical information is provided. Medicaid can only reimburse for medications for a medically accepted indication, so this would open the door for potential off-label use. Medicaid regulations would still have to be followed in addition to the new House File regulations. Pam Smith also pointed out that Medicaid does not always pay for the most convenient drug, either. In terms of grandfathering, the P&T Committee will sometimes determine when that will be used when they review medications and there is a PDL status change. However, their use of grandfathering is very specific and not just applicable to classes of drugs in general. Commission members were asked to review this legislation based on the current process of handling what IID language considers an "exception" as was discussed and to bring back any recommendations for changes/enhancements to processes to the August meeting.

Deflazacort (Emflaza): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Emflaza (deflazacort). Payment will be considered for patients when the following criteria are met:

1. *Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and*
2. *Patient is within the FDA labeled age; and*
3. *Patient experienced onset of weakness before 5 years of age; and*

4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose; and
6. Is dosed based on FDA approved dosing.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Larry Ambrosion motioned to accept the criteria as amended, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Hepatitis C Treatments: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C; and
2. Patient's age and/or weight is within the FDA labeled age and/or weight; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and
7. Patient has advanced liver disease corresponding to a Metavir score of 2 or greater fibrosis as confirmed by one of the following:
 - Liver biopsy confirming Metavir score \geq F2; or
 - Transient elastography (FibroScan) score \geq 7.5kPa; or
 - FibroSURE (FibroTest) score \geq 0.48; or
 - APRI score $>$ 0.7; or
 - Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or
 - Physical findings or clinical evidence consistent with cirrhosis; or
 - Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g.

vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.

8. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
9. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
10. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
11. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and
12. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and
13. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
 - a) Patient is not a pregnant female or male with a pregnant female partner; and
 - b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
 - c) Monthly pregnancy tests will be performed during treatment; and
14. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
15. Documentation is provided for patients who are ineligible to receive ribavirin.
16. Non-FDA approved or non-compensated combination therapy regimens will not be approved.
17. Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.
18. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
19. Lost or stolen medication replacement requests will not be authorized.
20. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Mark Graber said looking at epidemiology, about 10% of patients per year with F2 Metavir criteria go on to F3. People with F1 may not progress. Given this information,

the members would like to modify the PA criteria to include those with a Metavir score of F2 or greater. Additionally, according to the guidelines, patients with a limited life expectancy that cannot be remediated by treating HCV, transplantation, or other directed therapy do not require treatment, as little evidence exists to support initiation of treatment in patients with limited life expectancies (less than twelve months) owing to non-liver-related comorbid conditions. Brett Faine motioned to accept the criteria as amended, and Larry Ambrosio seconded. The decision was unanimous. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting. New agents are expected to be released soon, so this will likely be reviewed again at future meetings.

Omalizumab (Xolair): The Commission feels that the medication should be limited to the Medical benefit based on the black box warning and the fact that the package insert further states "Administer Xolair only in a healthcare setting by healthcare providers prepared to manage anaphylaxis that can be life-threatening." Brett Faine motioned to remove coverage through the pharmacy benefit, and Larry Ambrosio seconded. The decision was unanimous. The recommended removal of coverage from the Pharmacy benefit will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Crisaborole (Eucrisa): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for Eucrisa (crisaborole). Payment will be considered for patients when the following criteria are met:

- 1. Patient has a diagnosis of mild to moderate atopic dermatitis; and*
- 2. Patient is within the FDA labeled age; and*
- 3. Patient has failed to respond to good skin care and regular use of emollients; and*
- 4. Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and*
- 5. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
- 6. Patient will continue with skin care regimen and regular use of emollients.*
- 7. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Brett Faine motioned to accept the criteria, and Daniel Gillette seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

Eluxadoline (Viberzi): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. *Patient is 18 years of age or older.*
2. *Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D).*
3. *Patient does not have any of the following contraindications to therapy:*
 - a. *Patient is without a gallbladder.*
 - b. *Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction.*
 - c. *Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day.*
 - d. *A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction).*
 - e. *Severe hepatic impairment (Child-Pugh Class C).*
 - f. *Severe constipation or sequelae from constipation.*
 - g. *Known or suspected mechanical gastrointestinal obstruction.*
4. *Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:*
 - a. *A preferred antispasmodic agent (dicyclomine or hyoscyamine).*
 - b. *A preferred antidiarrheal agent (loperamide).*

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. *Patient has not developed any contraindications to therapy (defined above).*
2. *Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:*
 - a. *Improvement in abdominal cramping or pain.*
 - b. *Improvement in stool frequency and consistency.*

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Kellen Ludvigson motioned to accept the criteria, and Larry Ambrosion seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

New to Market Drugs: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for newly marketed drugs. Payment will be considered for patients when the following criteria are met:

1. Patient has an FDA approved or compendia indication for the requested drug; and
2. If the requested drug falls in a therapeutic category/class with existing prior authorization criteria, the requested drug must meet the criteria for the same indication; or
3. If no clinical criteria are established for the requested drug, patient has tried and failed at least two preferred drugs, when available, from the Iowa Medicaid Preferred Drug List (PDL) for the submitted indication; and
4. Request must adhere to all FDA approved labeling.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Once newly marketed drugs are reviewed by the Pharmaceutical & Therapeutics Committee, they will be placed on the PDL which will dictate ongoing PA criteria, if applicable.

Daniel Gillette motioned to accept the criteria as modified, and Brett Faine seconded. All members were in favor. The recommended PA criteria will be sent to the medical/pharmacy associations for comment and brought back to the next DUR meeting.

High Dose Opioid (≥ 90 MME/day): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day. (See CDC Guideline for Prescribing Opioids for Chronic Pain at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and

5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
8. Chart notes from a recent office visit for pain management is included documenting the following:
 - a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
 - b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and
17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and
18. A documented dose reduction is attempted at least annually.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and

3. *Patient is not exhibiting warning signs of opioid use disorder; and*
4. *The benefits of opioids continue to outweigh the risks; and*
5. *A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and*
6. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and*
7. *Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.*
8. *Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and*
9. *Patient has been reeducated on opioid overdose prevention; and*
10. *Patient's household members have been reeducated on the signs of opioid overdose and how to administer naloxone.*

Given the additional burden this will create for the MCOs, the Commission agreed to initially only apply the criteria for new starts, and let existing users continue on their existing regimens for now, potentially addressing them in a future DUR focus study. They also suggested letters and calls to providers and members along with the customary informational letter. Pam Smith and the MCO representatives looked into how many members and providers will be impacted after the last meeting. Fee-for-service had 47 members (and 46 providers), AmeriHealth Caritas 904 members, Amerigroup 1694 members (and 612 providers), and United Healthcare 735 members. Susan Parker said a legislative opioid commission is being created to seek input from organizations and states and provide a report, and it could potentially suggest additional criteria or quantity limits. Since the data reported varied by program, Pam Smith will work with the MCOs to define parameters to ensure all four programs use the same data points. The information will be brought back to the next meeting for further discussion.

GLP-1 Agonist/Basal Insulin Combinations: The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met:

1. *A diagnosis of type 2 diabetes mellitus; and*
2. *Patient is 18 years of age or older; and*
3. *The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and*

4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and
5. Will not be used concurrently with prandial insulin; and
6. Clinical rationale is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and
7. Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:
 - a. Soliqua below 15 units or over 60 units, or
 - b. Xultophy persistently below 16 units or over 50 units.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Calcifediol (Rayaldee): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for calcifediol (Rayaldee). Initial requests will be considered for patients when the following criteria are met:

1. Patient is 18 years of age or older; and
2. Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and
3. Patient is not on dialysis; and
4. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past 3 months; and
5. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of 3 months.
6. Initial requests will be considered for a dose of 30 mcg once daily for 3 months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and
2. Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Lesinurad (Zurampic): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests will be considered for patients when the following criteria are met:

- 1. Patient is 18 years of age or older; and*
- 2. Patient has a diagnosis of hyperuricemia associated with gout; and*
- 3. Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least 3 months; and*
- 4. Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and*
- 5. Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and*
- 6. Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.*
 - a. If taking allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min); and*
- 7. Patient does not have a contraindication to therapy including any of the following:*
 - a. Severe renal impairment (eCrCl < 30 mL/min),*
 - b. End stage renal disease,*
 - c. Kidney transplant recipient,*
 - d. On dialysis,*
 - e. Tumor lysis syndrome, or*
 - f. Lesch-Nyhan syndrome.*

If criteria for coverage are met, initial requests will be given for 6 months. Continuation of therapy will be considered when the following criteria are met:

- 1. Patient continues to take medication in combination with a xanthine oxidase inhibitor.*
 - a. If allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min)*
- 2. Patient has an eCrCl > 45 mL/min; and*
- 3. Patient does not have a contraindication to therapy including any of the following:*
 - a. Severe renal impairment (eCrCl < 30 mL/min),*
 - b. End stage renal disease,*
 - c. Kidney transplant recipient,*
 - d. On dialysis,*
 - e. Tumor lysis syndrome, or*
 - f. Lesch-Nyhan syndrome.*

4. *Documentation of a positive clinical response to lesinurad.*

The required trials may be overridden when documented evidence is provided that use of the agent(s) would be medically contraindicated.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Sapropterin (Kuvan): The Commission reviewed the prior authorization criteria as follows:

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

- 1. Patient has a diagnosis of phenylketonuria (PKU); and*
- 2. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and*
- 3. Patient has a baseline blood Phe level ≥ 360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and*
- 4. Patient's current weight is provided; and*
- 5. Request is for an FDA approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and*
- 6. Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy.*

Initial requests will be considered for 1 month to assess response to therapy.

Continuation of therapy will be considered when the following criteria are met:

- 1. Patient's current weight is provided; and*
- 2. Patient continues on a Phe restricted diet; and*
- 3. For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy.*
- 4. For patients initiated at a dose of 20mg/kg/per day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.*
- 5. Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals.*

Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.

As this was the second review of these criteria, no motion was necessary. The recommendation will be sent to the Department for consideration.

Miscellaneous

DUR Digest: The Commission members conducted the second review of the draft DUR Digest Volume 29, Number 3. There were not recommended changes. The DUR Digest will be posted to the DUR website.

MedWatch: The Commission members received FDA announcements concerning new Black Box Warnings.

At 11:55, Larry Ambroson motioned to adjourn the meeting and Daniel Gillette and Brian Couse both seconded. (No closed session was needed due to lack of profile review post MCO transition.)

The next meeting will be held at 9:30 a.m. on Wednesday, August 2, 2017, at the Learning Resource Center in West Des Moines.

Appendix J

Mental Health Advisory Group

Mental Health Advisory Group

The Iowa Medicaid Drug Utilization Review Mental Health Advisory Group (MHAG), formerly known as the Mental Health Work Group, was established in SFY08. It is currently comprised of two members of the Drug Utilization Review Commission (psychiatrist and pharmacist), several pediatric and adolescent psychiatrists, an adult psychiatrist, a psychiatric pharmacist, a pediatrician and a psychiatrist from Magellan Health Services.

The Mental Health Advisory Group is a separate entity from the Iowa Medicaid Drug Utilization Review (DUR) Commission. All recommendations from the MHAG must be approved by the DUR Commission before they can be implemented.

The original goal of the MHWG was to address issues that developed specific to the pediatric and adolescent psychiatrists within the State of Iowa when mental health drug consolidation edits were implemented in October, 2007. Since then, the DUR Commission has made the decision to refer other mental health issues that impact the entire mental health population of Iowa Medicaid, regardless of the members' age.

The MHAG did not meet in SFY17 as the DUR Commission did not request a topic be referred to the MHAG.

Appendix K

Recommendations to the P&T

P & T Recommendations SFY17

The DUR Commission makes recommendations to the Iowa Medicaid Pharmaceutical & Therapeutics (P&T) Committee regarding the status of a medication on the Preferred Drug List (PDL) as issues arise. During the time period for this report there were no recommendations made to the P&T Committee.

Appendix L

Useful Links

Iowa Drug Utilization Review (DUR) Commission Useful Links

DUR Website

<http://iadur.org/>

DUR Newsletters

<http://iadur.org/newsletters>

Prevalence Reports

To view prevalence reports, visit the link below under Packets. Each packet included the bi-monthly prevalence report reviewed by the DUR Commission.

<http://iadur.org/agendas>